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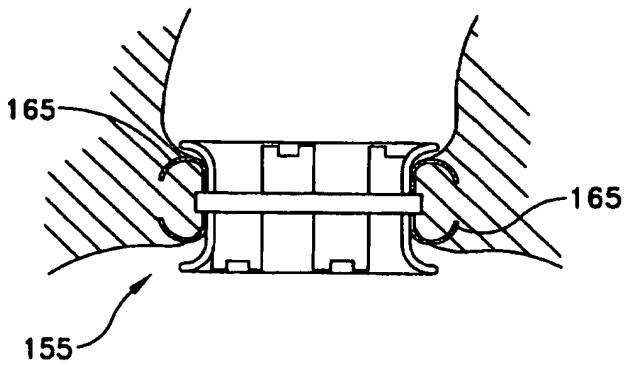
(54) Title: FIXATION BAND FOR AFFIXING A PROSTHETIC HEART VALVE TO TISSUE



(57) Abstract: A fixation band (155) for affixing a prosthetic heart valve to tissue, the fixation band (155) comprising: a structure having a proximal end and a distal end in opposition to one another, and a lateral region between the proximal end and the distal end, wherein the prosthetic heart valve is attached to one of the proximal end and the distal end of the structure; a plurality of barbs (165) selectively configurable between a first position and a second position, the barbs (165) being contained within a peripheral boundary of the lateral region of the structure in the first position, and the barbs (165) being extended from the peripheral boundary of the lateral region of the structure in the second position; and an actuator for selectively moving the plurality of barbs (165) between the first position and the second position.

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FIXATION BAND FOR AFFIXING A PROSTHETIC HEART VALVE TO TISSUE

Reference To Pending Prior Patent Applications

This patent application:

(1) is a continuation-in-part of pending prior U.S. Patent Application Serial No. 09/949,061, filed 09/07/01 by John R. Liddicoat for FIXATION BAND FOR AFFIXING A PROSTHETIC HEART VALVE TO TISSUE (Attorney's Docket No. VIA-11); and

(2) claims benefit of pending prior U.S. Provisional Patent Application Serial No. 60/373,059, filed 04/16/2002 by Steven B. Woolfson et al. for FIXATION BAND FOR AFFIXING A PROSTHETIC HEART VALVE TO TISSUE (Attorney's Docket No. VIA-2425 PROV).

The aforementioned two patent applications are hereby incorporated herein by reference.

Field Of The Invention

This invention relates to surgical apparatus in general, and more particularly to prosthetic heart valves.

Background Of The Invention

The human heart consists of four chambers: the right atrium for receiving blood from systemic circulation; the right ventricle for receiving blood from the right atrium and pumping it to the lungs; the left atrium for receiving oxygenated blood from the lungs; and the left ventricle for receiving oxygenated blood from the left atrium and pumping it to systemic circulation.

The human heart also consists of four valves: the tricuspid valve located between the right atrium and the right ventricle; the pulmonary valve located at the output of the right ventricle; the mitral valve located between the left atrium and the left ventricle; and the aortic valve located at the output of the left ventricle.

In some circumstances (e.g., a birth defect, disease, etc.) a natural heart valve may need to be replaced by a prosthetic heart valve. In this situation, sometimes referred to as "on pump" surgery, the patient must be placed on a heart-lung machine and the heart stopped while the defective heart valve is removed and the prosthetic heart valve installed through a major incision made in the wall of the heart. The prosthetic heart valve is typically sutured in place at the annulus, or seat, of the natural heart valve using a sewing cuff disposed about the circular periphery of the prosthetic heart valve.

While such surgery is typically successful, it is also highly traumatic to the body and the use of the heart-lung machine may raise issues of subtle mental impairment in the near term following surgery.

In view of the trauma associated with a major heart wall incision and possible subtle mental impairment which may be associated with the use of a heart-lung machine, it has been proposed to effect valve replacement without placing the patient on a heart-lung machine and stopping the heart. See, for

example, PCT Patent Application No. PCT/US00/02126, filed 01/27/00 by Gregory Lambrecht et al. for CARDIAC VALVE PROCEDURE METHODS AND DEVICES, published 8/3/00 as PCT Patent Publication No. WO 00/44313. This type of surgery is sometimes referred to as "off-pump", or "beating heart", surgery.

It has been recognized that if a heart valve is to be replaced with "off-pump", "beating heart" surgery, the incisions made into the vascular system should be as small as possible. However, this can make it difficult to secure the prosthetic heart valve in place, since the prosthetic heart valve is typically sutured to the annulus, or seat, of the natural heart valve, and since suturing (including knot tying) can be difficult to effect through small incisions. This can be particularly true where the incisions may be made into the vascular system at a location remote from the valve seat, e.g., in the superior vena cava in the case of the tricuspid valve, or in the pulmonary artery in the case of the pulmonary valve, or the pulmonary veins in the case of the mitral valve, or the aorta in the case of the aortic valve.

Summary Of The Invention

As a result, one object of the present invention is to provide novel apparatus for quickly, easily and conveniently affixing a prosthetic heart valve in position within the heart.

Another object of the present invention is to provide a novel fixation band for affixing a prosthetic heart valve in position within the heart.

And another object of the present invention is to provide a novel method for affixing a prosthetic heart valve in position within the heart.

These and other objects of the present invention are addressed by the provision and use of a novel fixation band for affixing a prosthetic heart valve in position within the heart.

In one preferred form of the invention, the fixation band generally comprises a tubular frame having a distal end and a proximal end, and a tube having a distal end and a proximal end. The tubular frame comprises a plurality of longitudinally-extending members each having a hook on its distal end and

fixation means on its proximal end. The tubular frame also comprises at least one laterally-extending member for stabilizing the longitudinally-extending members relative to one another so as to form the complete tubular frame. The tube is positioned inside the longitudinally-extending members, with the distal end of the tube being everted back over the aforementioned hooks. A sewing cuff is formed in the tube distal to the distalmost end of the longitudinally-extending members.

In use, a standard prosthetic valve is secured to the distal end of the fixation band by suturing the prosthetic valve's sewing cuff to the fixation band's sewing cuff. Next, the prosthetic valve, with fixation band attached, is advanced to the valve's seat. Then the fixation band's tubular frame is pulled proximally slightly. This action causes the ends of the hooks to pass through the side wall of the everted tube and into the surrounding tissue at the valve's seat, whereby the fixation band, and hence the prosthetic valve, will be fixed against further proximal movement. Next, the fixation band's fixation means are deployed so as to

secure the proximal end of the fixation band to the surrounding tissue, whereby the fixation band, and hence the prosthetic valve, will be fixed against distal movement.

In one form of the invention, the fixation means may be deployed by bending them radially outwardly so that they engage the surrounding tissue.

In another form of the present invention, the fixation means may be deployed by removing a restraining device, whereby the fixation means will automatically deploy against the surrounding tissue.

In another form of the present invention, there is provided a fixation band for affixing a prosthetic heart valve to tissue, the fixation band comprising: a structure having a proximal end and a distal end in opposition to one another, and a lateral region between the proximal end and the distal end, wherein the prosthetic heart valve is attached to one of the proximal end and the distal end of the structure; a plurality of barbs selectively configurable between a first position and a second position, the barbs being contained within a peripheral boundary of the lateral

region of the structure in the first position, and the barbs being extended from the peripheral boundary of the lateral region of the structure in the second position; and an actuator for selectively moving the plurality of barbs between the first position and the second position.

In another form of the present invention, there is provided a prosthetic heart valve assembly comprising: a prosthetic heart valve comprising a frame, at least one leaflet adapted to open and close relative to the frame; and a fixation band for affixing the prosthetic heart valve to tissue, the fixation band comprising: a structure having a proximal end and a distal end in opposition to one another, and a lateral region between the proximal end and the distal end, wherein the prosthetic heart valve is attached to one of the proximal end and the distal end of the structure; a plurality of barbs selectively configurable between a first position and a second position, the barbs being contained within a peripheral boundary of the lateral region of the structure in the first position, and the barbs being extended from the peripheral boundary of

the lateral region of the structure in the second position; and an actuator for selectively moving the plurality of barbs between the first position and the second position.

In another form of the present invention, there is provided a method for affixing a prosthetic heart valve to tissue, the method comprising: providing a fixation band for affixing a prosthetic heart valve to tissue, the fixation band comprising: a structure having a proximal end and a distal end in opposition to one another, and a lateral region between the proximal end and the distal end, wherein the prosthetic heart valve is attached to one of the proximal end and the distal end of the structure; a plurality of barbs selectively configurable between a first position and a second position, the barbs being contained within a peripheral boundary of the lateral region of the structure in the first position, and the barbs being extended from the peripheral boundary of the lateral region of the structure in the second position; and an actuator for selectively moving the plurality of barbs between the first position and the second position; positioning the

fixation band adjacent to the tissue; and actuating the fixation band so as to affix the prosthetic valve to tissue.

In another form of the present invention, there is provided a method for affixing a prosthetic heart valve to tissue, the method comprising: positioning a fixation band adjacent to the tissue; and removing a pin in engagement with a spring in a loaded configuration so as to release the spring, cause a cog to rotate, and deploy barbs through a lateral portion of the fixation band into the tissue surrounding the fixation band.

In another form of the present invention, there is provided a fixation band for affixing a prosthetic heart valve to tissue, the fixation band comprising: a proximal annular portion and a distal annular portion selectively positioned relatively to one another, the proximal annular portion and the distal annular portion each having a proximal side and a distal side, the proximal side of the distal annular portion and the distal side of the proximal annular portion being oriented toward one another, and the prosthetic heart

valve being attached to one of the distal side of the distal annular portion and the proximal side of the proximal annular portion; a plurality of staples configured between the distal side of the proximal annular portion and the proximal side of the distal annular portion; and a compression device in attachment to the proximal annular portion and the distal annular portion, the compression device being configured to selectively position the proximal annular member and the distal annular member toward one another so as to compress the plurality of staples therebetween and deploy the plurality of staples into tissue so as to affix the prosthetic heart valve to the tissue.

In another form of the present invention, there is provided a prosthetic heart valve assembly comprising: a prosthetic heart valve comprising a frame, and at least one leaflet adapted to open and close relative to the frame; and a fixation band for affixing a prosthetic heart valve to tissue, the fixation band comprising: a proximal annular portion and a distal annular portion selectively positioned relatively to one another, the proximal annular portion and the

distal annular portion each having a proximal side and a distal side, the proximal side of the distal annular portion and the distal side of the proximal annular portion being oriented toward one another, and the prosthetic heart valve being attached to one of the distal side of the distal annular portion and the proximal side of the proximal annular portion; a plurality of staples configured between the distal side of the proximal annular portion and the proximal side of the distal annular portion; and a compression device in attachment to the proximal annular portion and the distal annular portion, the compression device being configured to selectively position the proximal annular member and the distal annular member toward one another so as to compress the plurality of staples therebetween and deploy the plurality of staples into tissue so as to affix the prosthetic heart valve to the tissue.

In another form of the present invention, there is provided a method for affixing a prosthetic heart valve to tissue, the method comprising: providing a fixation band for affixing a prosthetic heart valve to tissue, the fixation band comprising: a proximal annular

portion and a distal annular portion selectively positioned relatively to one another, the proximal annular portion and the distal annular portion each having a proximal side and a distal side, the proximal side of the distal annular portion and the distal side of the proximal annular portion being oriented toward one another, and the prosthetic heart valve being attached to one of the distal side of the distal annular portion and the proximal side of the proximal annular portion; a plurality of staples configured between the distal side of the proximal annular portion and the proximal side of the distal annular portion; and a compression device in attachment to the proximal annular portion and the distal annular portion, the compression device being configured to selectively position the proximal annular member and the distal annular member toward one another so as to compress the plurality of staples therebetween and deploy the plurality of staples into tissue so as to affix the prosthetic heart valve to the tissue; positioning the fixation band adjacent to the tissue; and actuating the compression device so as to move the proximal annular

portion and the distal annular portion toward one another so as to deploy the plurality of staples into the tissue.

In another form of the present invention, there is provided a method for affixing a prosthetic heart valve to tissue, the method comprising: positioning a fixation band having the prosthetic heart valve attached thereto adjacent to the tissue; and actuating a compression device attached to the fixation band so as to move a proximal annular portion and a distal annular portion of the fixation band toward one another so as to deploy a plurality of staples into the tissue.

In another form of the present invention, there is provided a method for affixing a prosthetic heart valve to tissue, the method comprising: positioning a fixation band adjacent to tissue; actuating a compression device attached to the fixation band to move a proximal annular portion and a distal annular portion of the fixation band toward one another so as to deploy a plurality of staples into the tissue; and attaching the prosthetic heart valve to the fixation band.

Brief Description Of The Drawings

These and other objects and features of the present invention will be more fully disclosed or rendered obvious by the following detailed description of the preferred embodiments of the invention, which is to be considered together with the accompanying drawings wherein like numbers refer to like parts and further wherein:

Fig. 1 is a schematic view of a fixation band formed in accordance with the present invention;

Fig. 2 is a schematic view of the fixation band's tubular frame;

Fig. 3 is a schematic view of the fixation band's tube prior to its assembly with the tubular frame;

Fig. 4 is a schematic view of the complete fixation band shown in Fig. 1;

Fig. 5 is a schematic view showing a prosthetic heart valve secured to the fixation band of Fig. 1;

Fig. 6 is a schematic view showing the assembly of Fig. 5 after deployment of the fixation band's distal hooks;

Fig. 7 is a schematic view showing the assembly of Fig. 6 after deployment of the fixation band's proximal fixation means;

Fig. 8 is a schematic view showing a restraining device for restraining the fixation band's proximal fixation mean;

Figs. 9A-12B are schematic views showing a fixation apparatus having side deploying barbs;

Figs. 13A-13D are schematic views showing a heart valve replacement using the side deploying fixation apparatus shown in Figs. 9A-12B;

Figs. 14-30 are schematic views showing fixation apparatus having compression deploying barbs; and

Figs. 31 and 32 are schematic views showing a heart valve replacement using a left ventrical approach;

Figs. 33-35 are schematic views showing fixation of an prosthetic aortic heart valve at an annulus of the native aortic valve;

Figs. 36-39 are schematic views showing fixation of an prosthetic heart valve using snap fit means; and

Fig. 40 is a schematic view showing another embodiment of a prosthetic heart valve using snap fit means.

Detailed Description Of The Preferred Embodiments

Looking first at Fig. 1, there is shown a fixation band 5 which comprises one preferred form of the invention. Fixation band 5 generally comprises a tubular frame 10 and a tube 15.

Tubular frame 10 is shown in greater detail in Fig. 2. Tubular frame 10 generally comprises a distal end 20 and a proximal end 25. Tubular frame 10 comprises a plurality of longitudinally-extending members 30 each having a hook 35 on its distal end, and fixation means 40 (discussed in further detail below) on its proximal end. Tubular frame 10 also comprises at least one laterally-extending member 45 for stabilizing the longitudinally-extending members 30 relative to one another so as to form the complete tubular frame. In one form of the invention, each laterally-extending member 45 extends completely around the circumference of the frame, in the manner shown in

Fig. 2. Alternatively, a series of separate laterally-extending members 45 may be used to span the circumference of tubular frame 10. Furthermore, in one form of the invention, laterally-extending member 45 may be in the form of a circular hoop, like the hoop of a barrel, such as the laterally-extending member 47 shown in Fig. 2. Alternatively, and/or in addition, laterally-extending member 45 may have a serpentine configuration, such as the laterally-extending member 48 shown in Fig. 2.

Tube 15 is, initially, an ordinary straight tube such as is shown in Fig. 3, i.e., it is a hollow structure having a distal end 50, a proximal end 55 and a central lumen 60 extending therebetween. Tube 15 is preferably formed out of material which is easily incorporated in tissue, e.g., Dacron polyester or the like. Tube 15 may be vertically pleated or elastic, whereby to allow the material to stretch radially.

Tube 15 is preferably mounted to tubular frame 10 as follows. First, the distal end 50 of tube 15 is passed, distally, down the interior of tubular frame 10. Then the distal end 50 of tube 15 is everted (Fig.

4) so as to fold it back over, and cover, the hooks 35 of longitudinally-extending members 30.

As this is done, a sewing cuff 65 is formed in tube 15 distal to the distalmost end of longitudinally-extending members 30. Tube 15 may then be secured in this position, e.g., with sutures 70 maintaining sewing cuff 65 and with sutures 80 holding tube 15 to longitudinally-extending members 30.

In use, a standard prosthetic heart valve 85 (Fig. 5) is secured to the distal end of fixation band 5 by sewing the prosthetic heart valve's sewing cuff 90 to the fixation band's sewing cuff 65. Next, the prosthetic valve 85, with fixation band 5 attached, is advanced to the valve's seat. Then the fixation band's tubular frame 10 is pulled proximally slightly. This action causes the ends of the hooks 35 to pass through the side wall of the everted tube 15 (Fig. 6) and into the surrounding tissue T at the valve's seat, whereby fixation band 5, and hence prosthetic valve 85, will be fixed against further proximal movement. Next, the fixation band's fixation means 40 are deployed (Fig. 7) so as to secure the proximal end of the fixation band

to surrounding tissue, whereby the fixation band, and hence the prosthetic valve, will be fixed against distal movement. Where the fixation means 40 are secured to the proximal end of tube 15, the proximal end of tube 15 will follow the curvature of the deploying fixation means 40, such as is shown in Fig. 7. Alternatively, if fixation means 40 are free to move independently outboard relative to the proximal end of tube 40, either because they are not secured to tube 15 or they extend past the proximal end of the tube, fixation means 40 are free to move separately into the surrounding tissue.

In one form of the invention, fixation means 40 may be deployed by bending the proximal ends of longitudinally-extending members 30 outwardly, e.g., with an annular forming tool or a forceps-type device.

In another form of the invention, fixation means 40 may be deployed by removing a restraining device, e.g., a collar 87 (Fig. 8), whereby fixation means 40 will automatically deploy against the surrounding tissue.

Fixation band 5 may be used to affix prosthetic heart valve 85 to tissue in a conventional on-pump surgical procedure. Alternatively, and more preferably, fixation band 5 may be used to affix prosthetic heart valve 85 to tissue in a beating heart, off-pump surgical procedure. In this case, the assembled heart valve 85 and fixation band 5 are advanced to the intended valve seat by passing the assembly through an appropriate vascular pathway, e.g., in the case of the aortic valve, by passing the assembly down the aorta.

It should be appreciated that various modifications may be made to the preferred embodiments described above without departing from the scope of the present invention. Thus, for example, in the foregoing description, tubular frame 10 is described as being fully assembled (i.e., laterally-extending member 45 is secured to longitudinally-extending member 30) prior to being joined with tube 15 so as to form the complete fixation band 5. However, it should also be appreciated that longitudinally-extending members 30

and/or the laterally-extending member 45 may be secured to tube 15 prior to being joined to one another.

Furthermore, in the foregoing description, tube 15 is described as being, prior to eversion, an ordinary straight tube. However, if desired, tube 15 could be flared outwardly toward its distal end 50 to facilitate eversion over hooks 35, and/or it could include a radially-extending flange at its distal end to facilitate eversion over hooks 35, where the flange may be formed separately from the main body of the tube.

Referring next to Figs. 9A-13D, there is shown a side deploying apparatus 90 for affixing an prosthetic aortic heart valve 95 in position inside the aorta. Side deploying apparatus 90 is a multi-state device that can be safely guided into the aorta, properly positioned near the annulus of the native aortic valve, and then, by either automatic action or operator control, be deployed by means of introducing a number of barbs 100 into the aortic valve annulus. Side deploying apparatus 90 may also have the capability of its barbs 100 being retracted for either better positioning or removal.

Looking now at Figs. 9A-9D, in a preferred embodiment of the present invention, apparatus 90 comprises two shell portions 105 and two cog portions 110. In Fig. 9A, apparatus 90 is shown assembled and its barbs 100 deployed. In Fig. 9B, apparatus 90 is shown assembled, attached to a prosthetic valve 95 and its barbs 100 deployed, which keeps prosthetic valve 95 stationary relative to the wall of the aorta. Three significant features of shell 105 are: studs 115, which act as anchors for cog 110; the exit tracts 120, which allow for barbs 100 of cog 110 to exit shells 105; and the pinholes 125 through which actuating pins 130 (Fig. 11B) are inserted.

Looking now at Figs. 11A and 11B, cog 110 is shown in a "loaded" form inside shell 105. Two cogs 110 are the moving parts of apparatus 90 and reside sandwiched next to each other inside shells 105, but in opposing directions to one another. Referring again to Figs. 11A and 11B, cog 110 has several significant features integral to its function: eyelets 135, springs 140, barbs 100, and pinholes 142. When in the loaded state, springs 140 of cog 110 are stretched and barbs 100 are

folded down while studs 115 on shell 105 protrude through eyelets 135 and pins 130 are inserted through pinholes 142 so as to maintain the position of each cog 110 relative to shell 105.

Looking now at Figs. 12A and 12B, cog 110 is shown in the "deployed" form relative to shell 105. Here, barbs 100 are extended through exit tracts 120 and springs 140 are no longer stretched. Apparatus 90 can be transformed into the deployed state by removing pins 130 from pinholes 142 of each cog 110. When this happens, springs 140 each contract so as to rotate cog 110 relative to studs 115 of shell 105 and force barbs 100 out of exit tracks 120. To retract apparatus 90, force on pinholes 142 must be re-applied and cog 110 rotated back to its loaded position (see Figs. 11A and 11B).

Looking next at Figs. 13A-13D, there is shown an example of a typical heart valve replacement. In Fig. 13A, there is shown an aorta 145 with a native aortic valve 150. In Fig. 13B, aorta 145 is shown after valve 150 has been removed. In Fig. 13C, side deploying apparatus 90 is shown in an undeployed state (see Figs.

11A and 11B) inside aorta 145. In Fig. 13D, side deploying apparatus 90 is shown in a deployed state (see Figs. 12A and 12B) inside aorta 145.

In the preceding description, side deploying apparatus 90 is described in the context of affixing an prosthetic heart valve 95 in position within the aortic valve annulus. In this respect it should also be appreciated, however, that side deploying apparatus 90 may be used to affix some other heart valve within another cardiovascular structure.

Referring now to Figs. 14-40, there is shown an apparatus 155 (Fig. 14) for affixing an prosthetic aortic valve 160 (Fig. 17) in position inside the aortic valve annulus. Apparatus 155 is a compressive device that can be safely guided into the aorta, properly positioned near the annulus of the native aortic valve, and then, by either automatic action or operator control, deployed by means of advancing staples 165 (Fig. 17) into the aortic valve annulus. Compressive apparatus 155 may also have the capability of having its staples 165 retracted for either better positioning or removal of the apparatus. Compressive

apparatus 155 may be positioned for fixation above, below, or at the annulus of the native aortic valve. Compressive apparatus 155 may also be positioned using an aortic approach or a left ventricular approach so as to advance it toward the annulus of the native aortic valve.

Looking now at Figs. 14-22, in a preferred embodiment of the present invention, compressive apparatus 155 comprises a top ring 170 and a bottom ring 175 selectively positionable relative to one another by connector portions 180. Top ring 170 and bottom ring 175 each have a surface, forming an anvil 185, facing one another. In a preferred embodiment of the present invention, each anvil 185 (on top ring 170 and bottom ring 175) is shaped in an opening curve configuration so as to form a "C" shaped staple 165 (see Figs. 19) when deployed. In an alternative preferred embodiment of the present invention, each anvil 185 is shaped with a closing curve so as to form a "B" shaped staple (not shown) when deployed.

Looking next at Figs. 17-22, in a preferred embodiment of the invention, apparatus 155 includes

deployment means 190 for selectively actuating top ring 170 and bottom ring 175 relative to one another. Deployment means 190 generally comprise a handle 195, a plurality of cables 200 selectively connected to bottom ring 175 and extending to handle 195, and a support 205 selectively engaging top ring 170 and slidably connected to handle 200. In one preferred embodiment of the present invention, support 205 (see Fig. 16) comprises a solid component having passages 210 for blood flow formed therein. In another preferred embodiment of the invention, support 205 comprises three legs 215 (Fig. 17), which allow blood flow therebetween.

Now referring to Figs. 17-22, in a preferred embodiment of the present invention, there is shown the compressive apparatus 155 and the prosthetic aortic heart valve 160 in connection to one another. Preferably, this connection is performed prior to implantation, either in an operating room by a physician or a manufacturing site by a manufacturer. In another preferred embodiment of the present invention, apparatus 155 and prosthetic aortic heart

valve 160 are connected to one another in vivo, either prior to, or subsequent to, the fixation of apparatus 155 at or adjacent to an annulus of a native aortic heart valve (not shown).

Looking next at Figs. 17 and 18, apparatus 155 is shown prior to actuation, with top ring 170 and bottom ring 175 spaced apart from one another. While in this configuration, apparatus 155 is positioned at a desired deployment site, at or adjacent to the annulus of the native aortic valve (not shown).

Looking next at Figs. 19 and 20, apparatus 155 is shown subsequent to actuation, with top ring 170 and bottom ring 175 having been brought toward one another. In this configuration, staples 165 are deployed in a "C" configuration, extending away from each anvil 185, as top ring 170 and bottom ring 175 are drawn together. This deployment is effected by moving handle 195 away from support 205 (while applying a force on support 205 to prevent it from also moving with handle 195) so that cables 200 pull bottom ring 175 toward top ring 170, which is held stationary by legs 215.

Looking now at Figs. 21 and 22, deployment means 190 are shown disconnected from apparatus 155 and prosthetic aortic valve 160, with apparatus 155 shown configured for attachment at or adjacent to the annulus of a native aortic heart valve (not shown). Deployment means 190 is configured to disengage from apparatus 155 when handle 195 is moved away from apparatus 155 without holding support 205 stationary; as this occurs, cables 200 withdraw from bottom ring 175 and legs 215, which are pivotally attached together, collapse so that they can be withdrawn through a narrow opening.

Looking next at Figs. 23-25, apparatus 155 is shown being actuated by a tubular controller 220. Tubular controller 220 generally comprises a grasper 225 for selective attachment to handle 195, and a tube 230 surrounding grasper 225 for selectively engaging support 205. When compression apparatus 155 is to be deployed (i.e., when it is to have its rings 170 and 175 drawn together so as to deform the staples 165), tube 230 is held against support 205 while grasper 225 pulls handle 195 away from support 205. When deployment means 190 are to be withdrawn from

compression apparatus 155, tubular controller is withdrawn from compression apparatus 155 by simultaneously withdrawing both grasper 225 and tube 230.

Referring now to Figs. 26-29, there is shown apparatus 155 having a single anvil 185 for forming staple 165 into a "half-c" configuration. In this embodiment, apparatus 155 may be configured with a height of about half that of an apparatus 155 that forms a "C" configuration.

Looking now at Figs. 30-32, in a preferred embodiment of the present invention, there is shown apparatus being placed super-annular, i.e., on the aorta side of the aortic valve. This placement of apparatus 155 superior to the annulus is preferably performed using a left ventricle approach through the heart. For such a procedure, a collapsible support 205 may be used. Alternatively, a non-collapsible support (not shown) may be used. As shown in Fig. 31 and 32, a punch 235 may be used to resect the native aortic valve, with the punch approaching from either a left

ventricle approach (Fig. 31) or an aortic approach (Fig. 32).

Looking at Figs 33-35, in a preferred embodiment of the present invention, there is shown apparatus 155 being affixed to the annulus of the native heart valve. In this embodiment, staples 165 are placed at the annulus so as to hold apparatus 155 in place.

Looking next at Fig. 36, a fixation ring 237 is shown with snap fit means 238 for attachment of a prosthetic valve 239 to the fixation ring 237. Fixation ring 237 is deployed adjacent to the annulus of the native aortic valve and prosthesis 239 is snap fit to fixation ring 237 using snap fit means 238.

Looking next at Figs. 37-40, in a preferred embodiment of the present invention, there is shown apparatus 155 configured with spring snaps 240 for attachment of a prosthesis 245 to apparatus 155. Prosthesis 245 may be secured to apparatus 155 after attachment of apparatus 155 to the annulus is completed.

In the preceding description, compressive apparatus 155 is described in the context of affixing a

prosthetic heart valve in position within the aorta. In this respect it should be appreciated, however, that compressive apparatus 155 may be used to affix some other heart valve within another cardiovascular structure.

Still other modifications and variations will be apparent to those skilled in the art in view of the present disclosure, and are considered to be within the scope of the present invention.

What Is Claimed Is:

1. A fixation band for affixing a prosthetic heart valve to tissue, the fixation band comprising:

a structure having a proximal end and a distal end in opposition to one another, and a lateral region between the proximal end and the distal end, wherein the prosthetic heart valve is attached to one of the proximal end and the distal end of the structure;

a plurality of barbs selectively configurable between a first position and a second position, the barbs being contained within a peripheral boundary of the lateral region of the structure in the first position, and the barbs being extended from the peripheral boundary of the lateral region of the structure in the second position; and

an actuator for selectively moving the plurality of barbs between the first position and the second position.

2. A fixation band according to claim 1 wherein the structure comprises a proximal shell portion and a distal shell position.

3. A fixation band according to claim 2 wherein at least one of the proximal shell portion and the distal shell portion comprises a plurality of exit tracts for the barbs to pass through when moving between the first position and the second position.

4. A fixation band according to claim 3 wherein the actuator comprises at least one cog disposed between the proximal shell portion and the distal shell portion, the at least one cog comprising at least one spring being selectively configurable between a loaded state and an unloaded state, wherein the barbs are selectively positioned in the first position within the peripheral boundary of the lateral region of the structure when the at least one spring is configured in the loaded state, and the barbs are selectively positioned in the second position outside the peripheral boundary of the lateral region of the

structure when the at least one spring is configured in the unloaded state.

5. A fixation band according to claim 4 further comprising an attachment between a portion of each one of the at least one spring and one of the proximal shell portion and the distal shell portion, and a selectively releasable attachment between the at least one cog and at least one of the proximal shell portion and the distal shell portion, wherein release of the selectively releasable attachment causes the spring to change from the loaded state to the unloaded state so as to move the at least one cog relative to the at least one of the proximal shell portion and the distal shell portion so as to move the barbs from the first position to the second position.

6. A fixation band according to claim 5 wherein the at least one cog forms at least one first pin hole therein, at least one of the proximal shell portions and the distal shell portions forms at least one second pin hole therein corresponding to the at least one

first pin hole of the at least one cog, and wherein the fixation band further comprises at least one pin configured for selective placement within a set of the at least one first pin hole and the at least one second pin hole corresponding to one another so as to selectively maintain the at least one spring of the cog in the loaded state with the barbs at the first position.

7. A fixation band according to claim 6 wherein the at least one spring is configured in the loaded state by maintaining the at least one spring in tension with the at least one pin placed within the set of the at least one first pin hole and the at least second pin hole.

8. A fixation band according to claim 1 wherein the prosthetic heart valve and the fixation band are attached to one another during manufacture of the prosthetic band.

9. A fixation band according to claim 1 wherein prosthetic heart valve and the fixation band are attached to one another subsequent to manufacture of the fixation band.

10. A prosthetic heart valve assembly comprising:

a prosthetic heart valve comprising a frame, at least one leaflet adapted to open and close relative to the frame; and

a fixation band for affixing the prosthetic heart valve to tissue, the fixation band comprising:

a structure having a proximal end and a distal end in opposition to one another, and a lateral region between the proximal end and the distal end, wherein the prosthetic heart valve is attached to one of the proximal end and the distal end of the structure;

a plurality of barbs selectively configurable between a first position and a second position, the barbs being contained within a peripheral boundary of the lateral region of the structure in the first position, and the barbs being extended from the

peripheral boundary of the lateral region of the structure in the second position; and

an actuator for selectively moving the plurality of barbs between the first position and the second position.

11. A method for affixing a prosthetic heart valve to tissue, the method comprising:

providing a fixation band for affixing a prosthetic heart valve to tissue, the fixation band comprising:

a structure having a proximal end and a distal end in opposition to one another, and a lateral region between the proximal end and the distal end, wherein the prosthetic heart valve is attached to one of the proximal end and the distal end of the structure;

a plurality of barbs selectively configurable between a first position and a second position, the barbs being contained within a peripheral boundary of the lateral region of the structure in the first position, and the barbs being extended from the

peripheral boundary of the lateral region of the structure in the second position; and

an actuator for selectively moving the plurality of barbs between the first position and the second position;

positioning the fixation band adjacent to the tissue; and

actuating the fixation band so as to affix the prosthetic valve to tissue.

12. A method for affixing a prosthetic heart valve to tissue, the method comprising:

positioning a fixation band adjacent to the tissue; and

removing a pin in engagement with a spring in a loaded configuration so as to release the spring, cause a cog to rotate, and deploy barbs through a lateral portion of the fixation band into the tissue surrounding the fixation band.

13. A fixation band for affixing a prosthetic heart valve to tissue, the fixation band comprising:

a proximal annular portion and a distal annular portion selectively positioned relatively to one another, the proximal annular portion and the distal annular portion each having a proximal side and a distal side, the proximal side of the distal annular portion and the distal side of the proximal annular portion being oriented toward one another, and the prosthetic heart valve being attached to one of the distal side of the distal annular portion and the proximal side of the proximal annular portion;

a plurality of staples configured between the distal side of the proximal annular portion and the proximal side of the distal annular portion; and

a compression device in attachment to the proximal annular portion and the distal annular portion, the compression device being configured to selectively position the proximal annular member and the distal annular member toward one another so as to compress the plurality of staples therebetween and deploy the plurality of staples into tissue so as to affix the prosthetic heart valve to the tissue.

14. A fixation band according to claim 13 wherein at least one of the proximal annular member and the distal annular member forms an anvil so as to bend a portion of the staples toward the tissue.

15. A fixation band according to claim 13 wherein the proximal annular member and the distal annular member form a first anvil and a second anvil so as to bend a first portion of the staples and a second portion of the staples, respectively.

16. A fixation band according to claim 15 wherein the first anvil and the second anvil form an opened curve with respect to one another so as to form a "C" shaped staple therebetween.

17. A fixation band according to claim 15 wherein the first anvil and the second anvil form a closed curve with respect to one another so as to form a "B" shaped staple therebetween.

18. A fixation band according to claim 13 wherein the plurality of staples have a first end and a second end, and the first end of each one of the plurality of staples is attached to the first annular portion.

19. A fixation band according to claim 13 further comprising a band connecting together the plurality of staples.

20. A fixation band according to claim 13 wherein the compression device comprises a support engaging the proximal annular portion and a plurality of cables connected to the distal annular portion, and further wherein the plurality of cables are configured to be drawn through the support so as to move the proximal annular portion and the distal annular portion toward one another.

21. A fixation band according to claim 20 wherein the plurality of cables are selectively attached to the distal annular portion so as to disconnect the

compression device after the staples are deployed into the tissue.

22. A fixation band according to claim 13 wherein the compression device is selectively attached to the proximal annular portion and the distal annular portion so as to disconnect the compression device after the staples are deployed into the tissue.

23. A prosthetic heart valve assembly comprising:

a prosthetic heart valve comprising a frame, and at least one leaflet adapted to open and close relative to the frame; and

a fixation band for affixing a prosthetic heart valve to tissue, the fixation band comprising:

a proximal annular portion and a distal annular portion selectively positioned relatively to one another, the proximal annular portion and the distal annular portion each having a proximal side and a distal side, the proximal side of the distal annular portion and the distal side of the proximal annular

portion being oriented toward one another, and the prosthetic heart valve being attached to one of the distal side of the distal annular portion and the proximal side of the proximal annular portion;

a plurality of staples configured between the distal side of the proximal annular portion and the proximal side of the distal annular portion; and

a compression device in attachment to the proximal annular portion and the distal annular portion, the compression device being configured to selectively position the proximal annular member and the distal annular member toward one another so as to compress the plurality of staples therebetween and deploy the plurality of staples into tissue so as to affix the prosthetic heart valve to the tissue.

24. A method for affixing a prosthetic heart valve to tissue, the method comprising:

providing a fixation band for affixing a prosthetic heart valve to tissue, the fixation band comprising:

a proximal annular portion and a distal annular portion selectively positioned relatively to one another, the proximal annular portion and the distal annular portion each having a proximal side and a distal side, the proximal side of the distal annular portion and the distal side of the proximal annular portion being oriented toward one another, and the prosthetic heart valve being attached to one of the distal side of the distal annular portion and the proximal side of the proximal annular portion;

a plurality of staples configured between the distal side of the proximal annular portion and the proximal side of the distal annular portion; and

a compression device in attachment to the proximal annular portion and the distal annular portion, the compression device being configured to selectively position the proximal annular member and the distal annular member toward one another so as to compress the plurality of staples therebetween and deploy the plurality of staples into tissue so as to affix the prosthetic heart valve to the tissue;

positioning the fixation band adjacent to the tissue; and

actuating the compression device so as to move the proximal annular portion and the distal annular portion toward one another so as to deploy the plurality of staples into the tissue.

25. A method according to claim 24 further comprising the step of removing the compression device from the proximal annular portion and the distal annular portion.

26. A method for affixing a prosthetic heart valve to tissue, the method comprising:

positioning a fixation band having the prosthetic heart valve attached thereto adjacent to the tissue; and

actuating a compression device attached to the fixation band so as to move a proximal annular portion and a distal annular portion of the fixation band toward one another so as to deploy a plurality of staples into the tissue.

27. A method for affixing a prosthetic heart valve to tissue, the method comprising:

positioning a fixation band adjacent to tissue;

actuating a compression device attached to the fixation band to move a proximal annular portion and a distal annular portion of the fixation band toward one another so as to deploy a plurality of staples into the tissue; and

attaching the prosthetic heart valve to the fixation band.

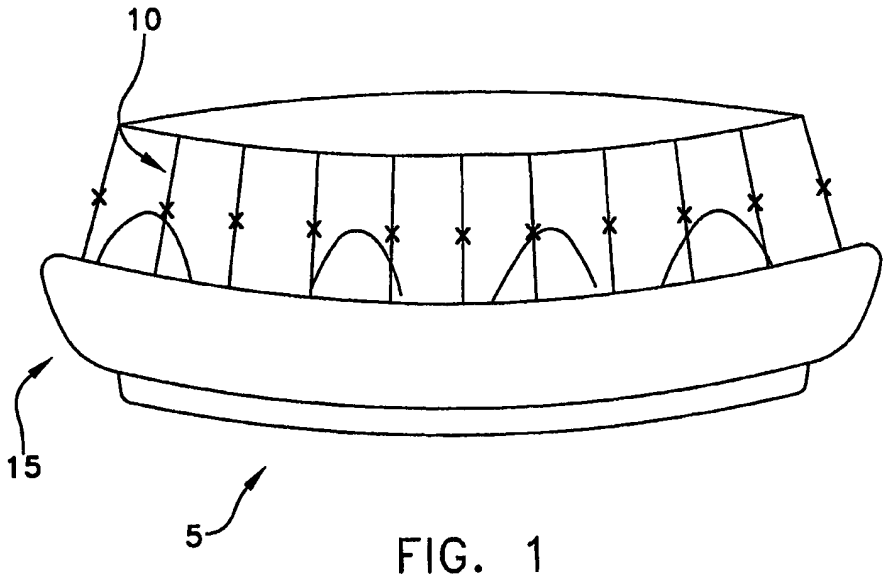

FIG. 1

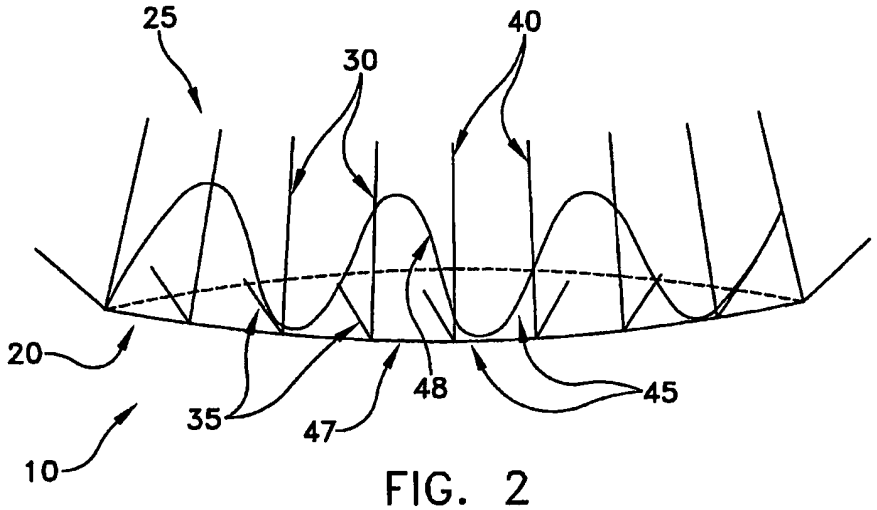

FIG. 2

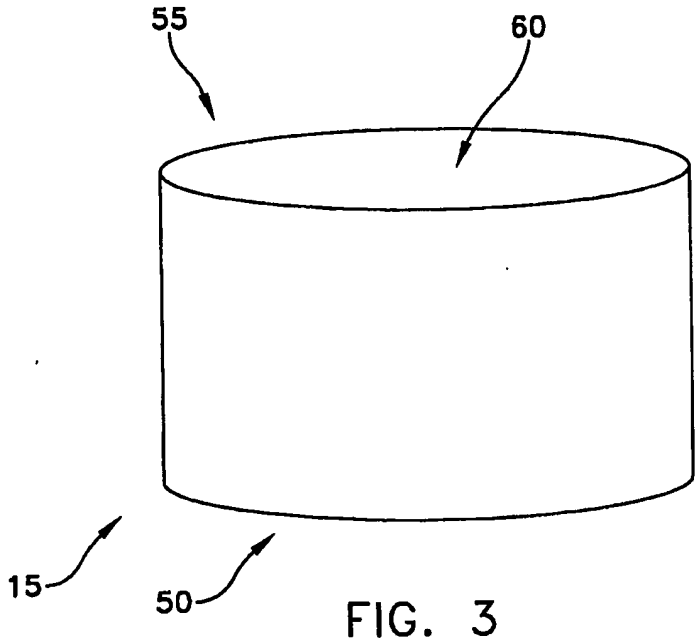

FIG. 3

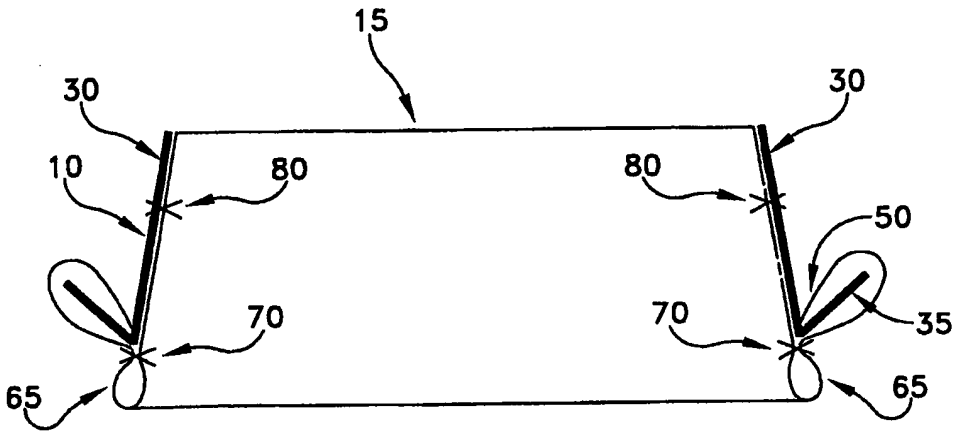

FIG. 4

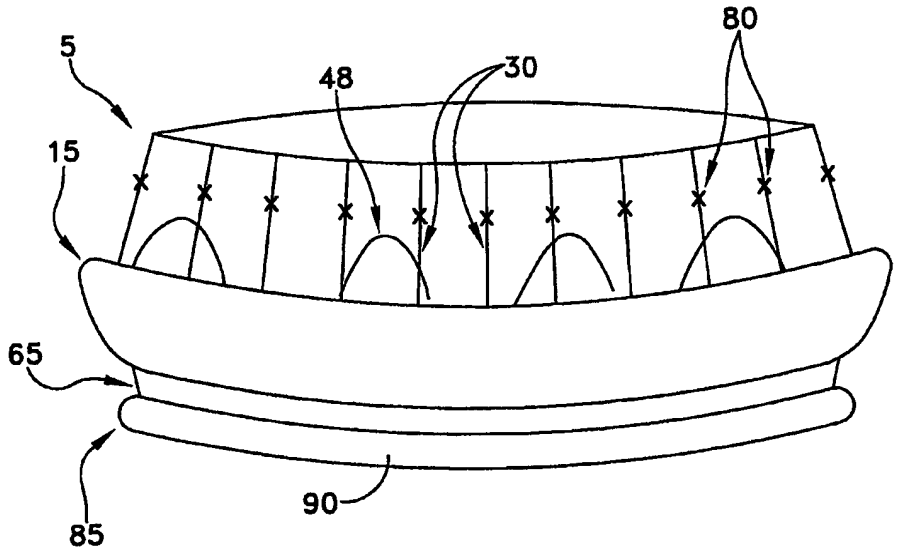

FIG. 5

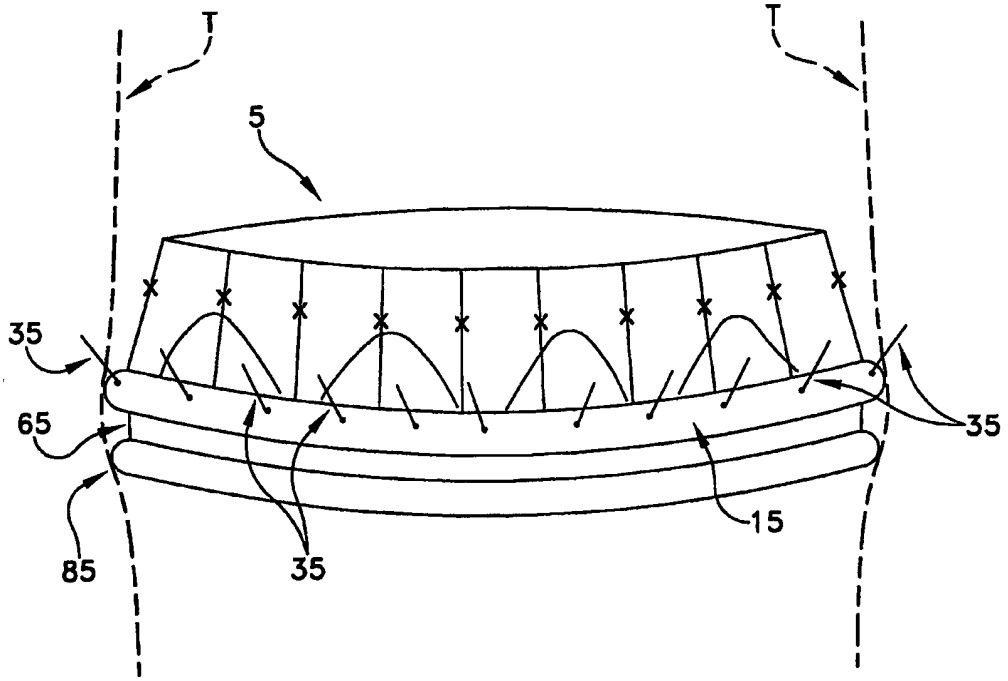

FIG. 6

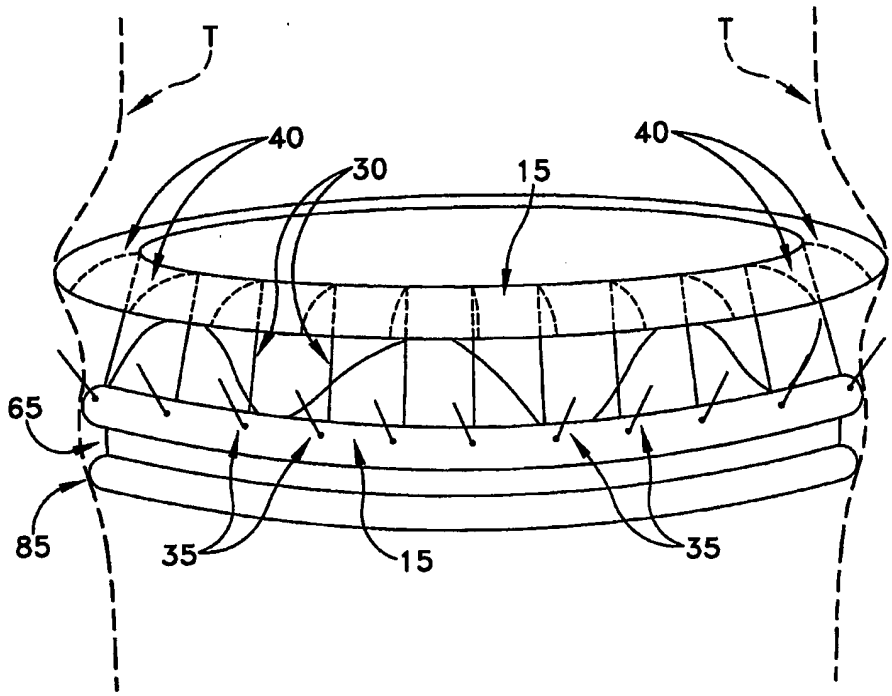

FIG. 7

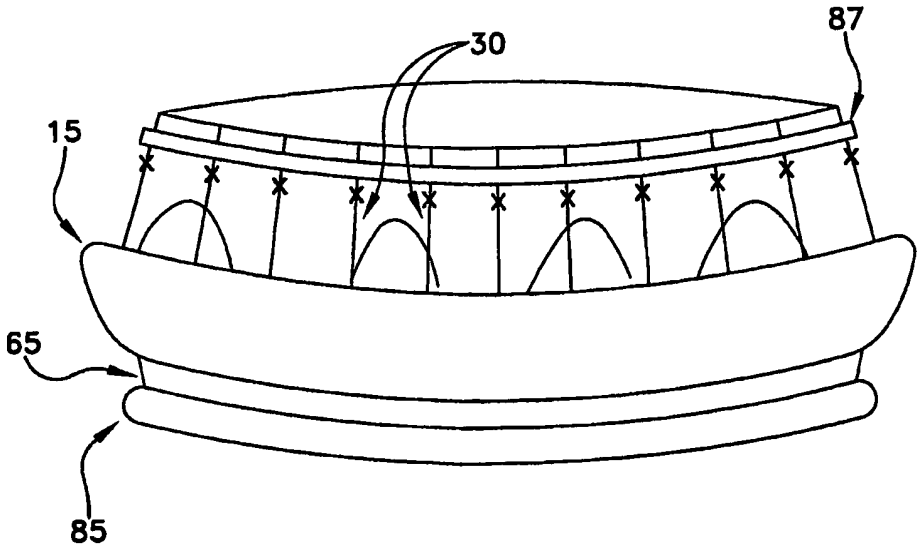

FIG. 8

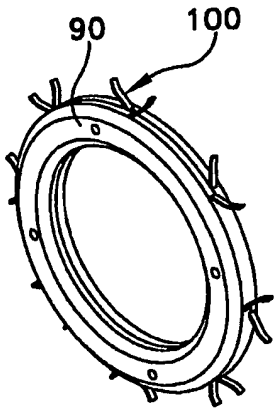

FIG. 9A

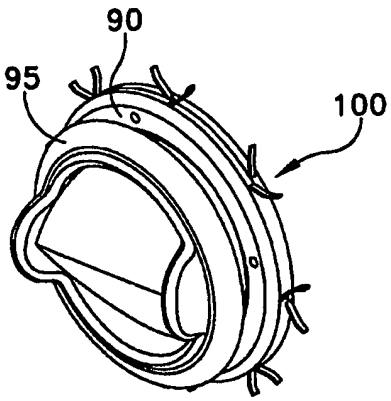

FIG. 9B

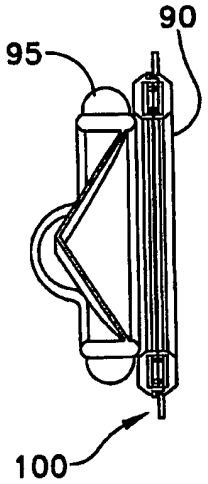

FIG. 9C

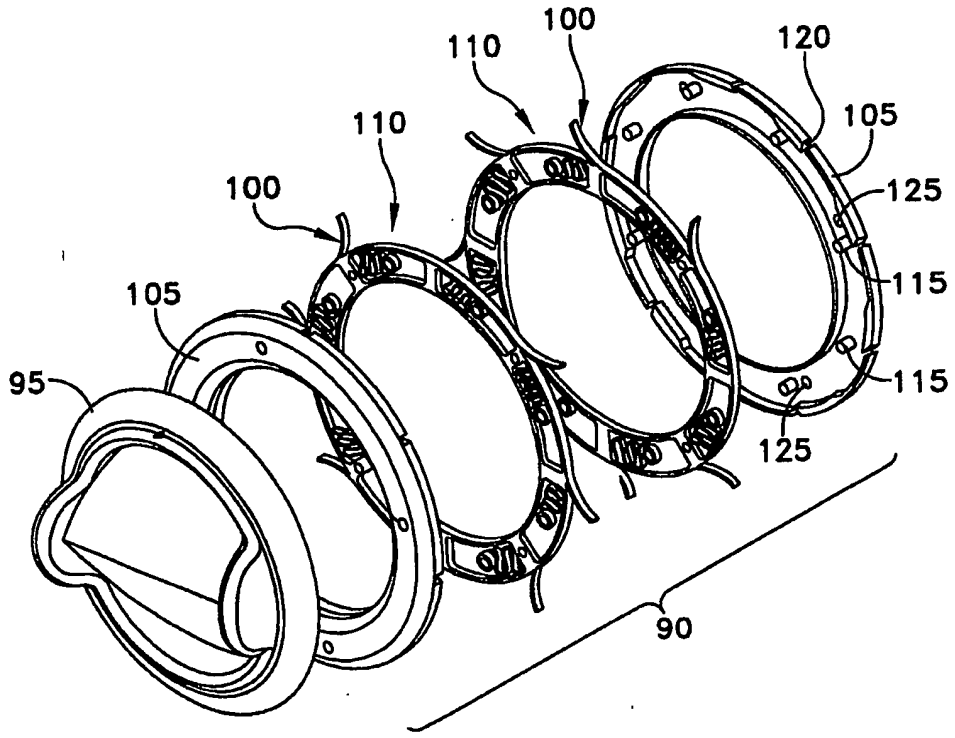

FIG. 9D

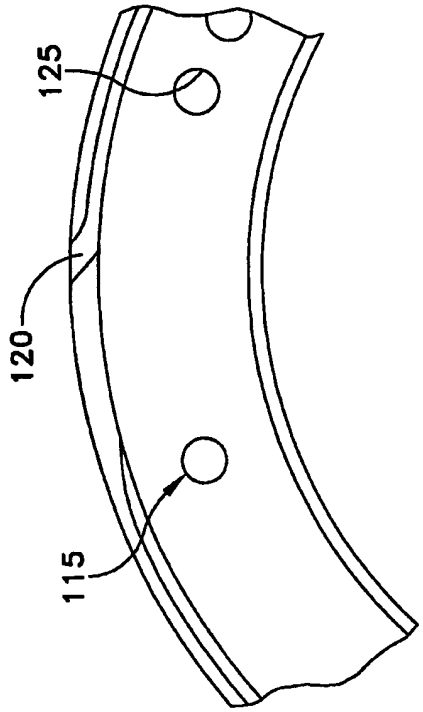

FIG. 10B

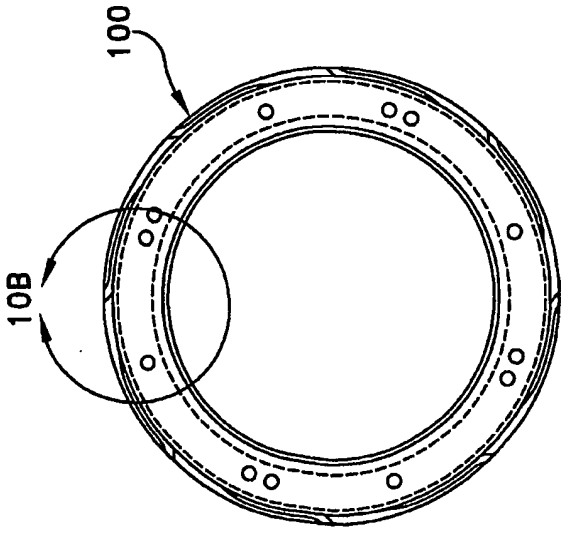

FIG. 10A

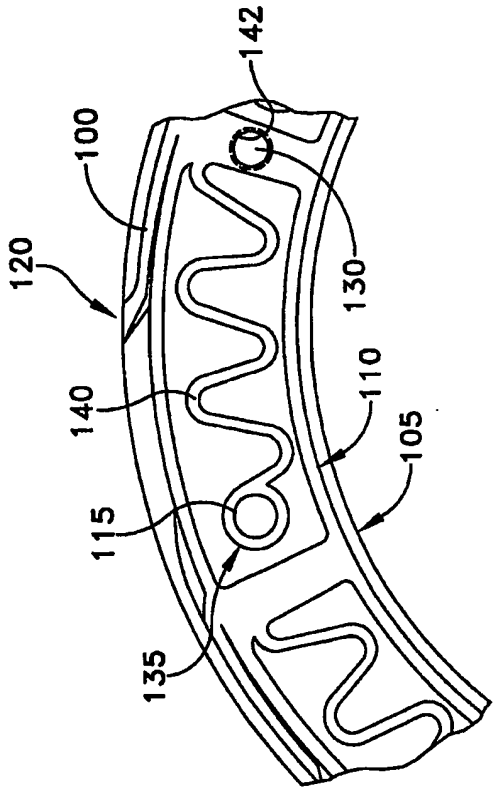

FIG. 11B

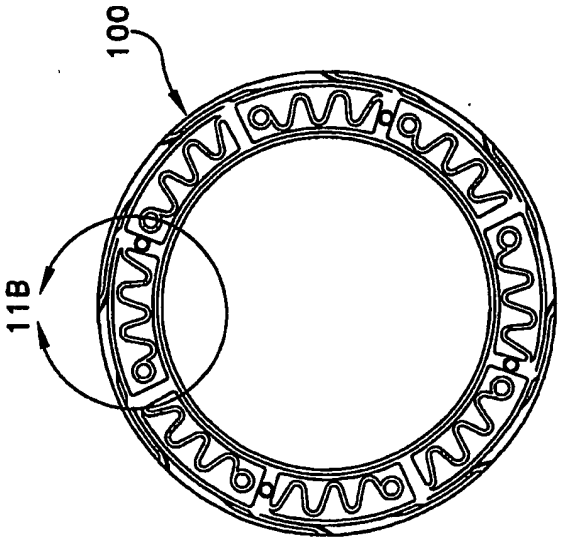

FIG. 11A

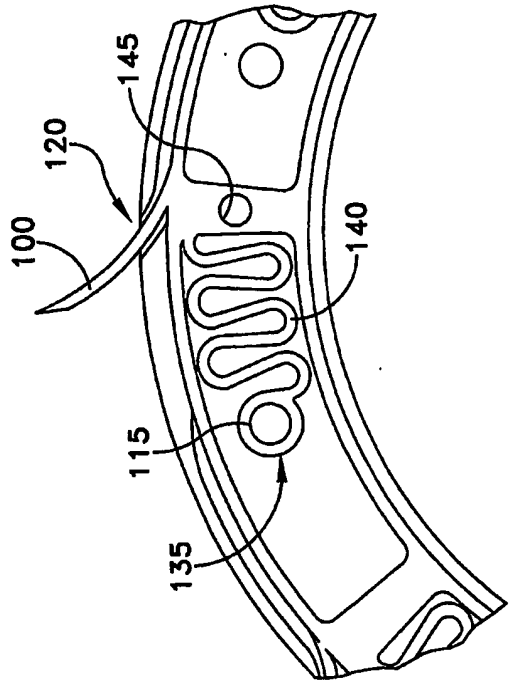

FIG. 12B

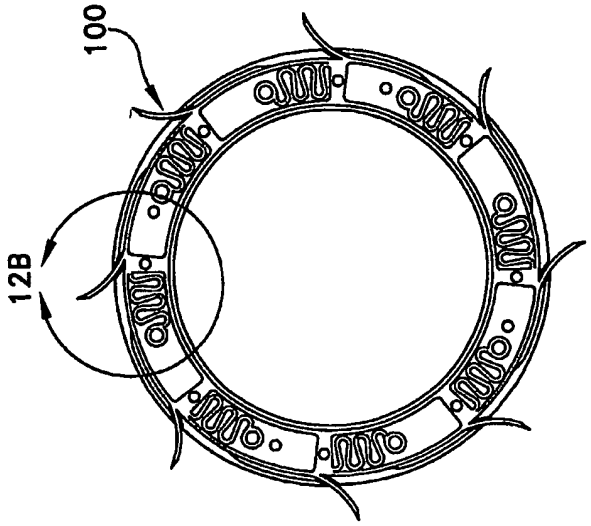

FIG. 12A

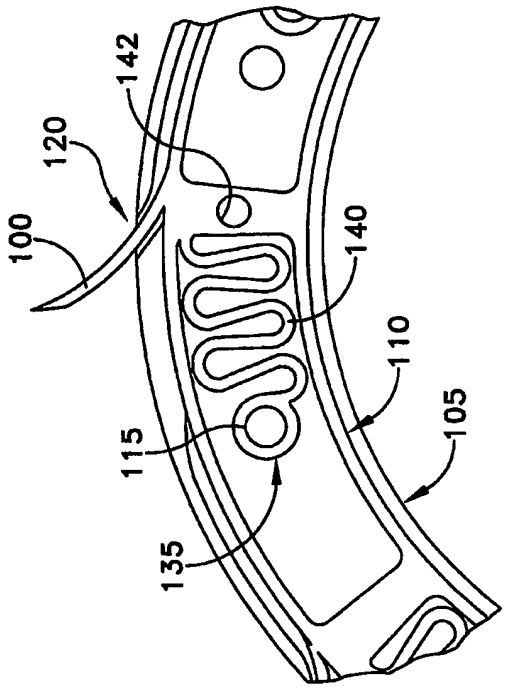

FIG. 12B

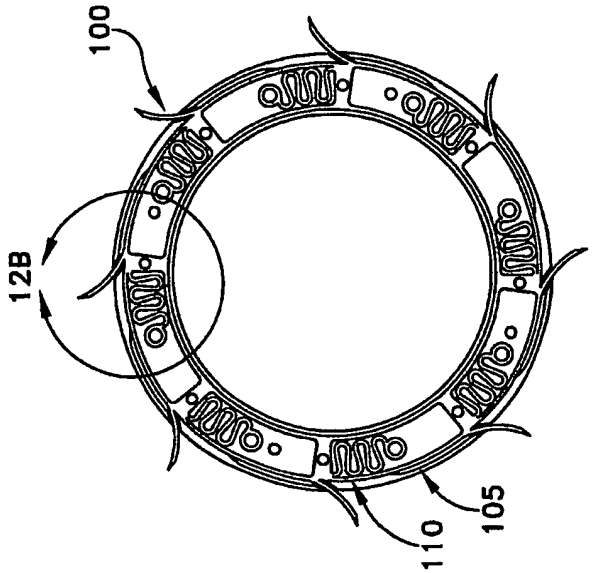

FIG. 12A

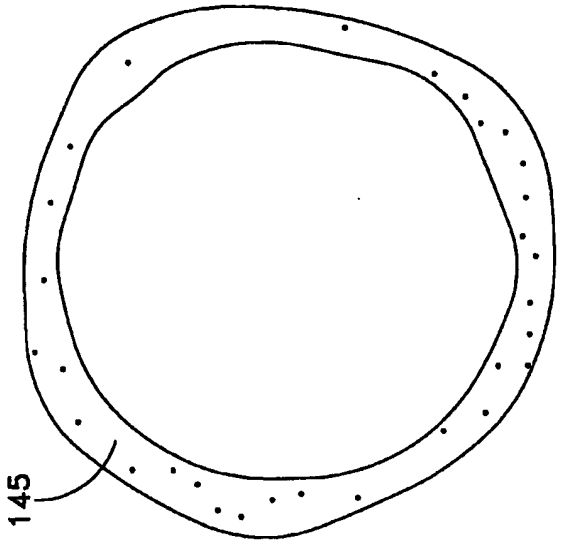

FIG. 13B

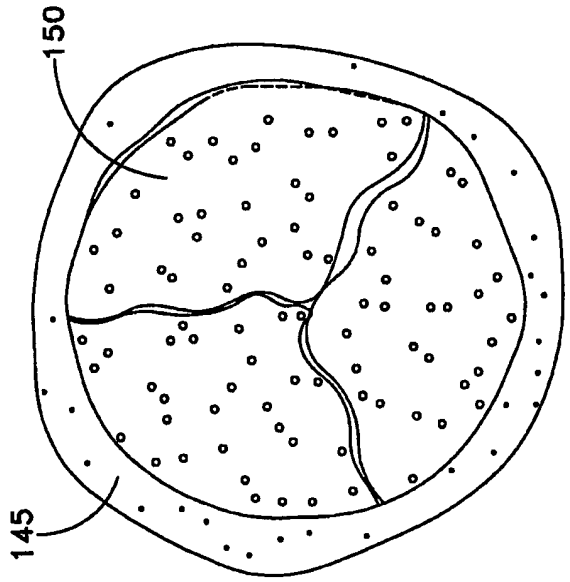

FIG. 13A

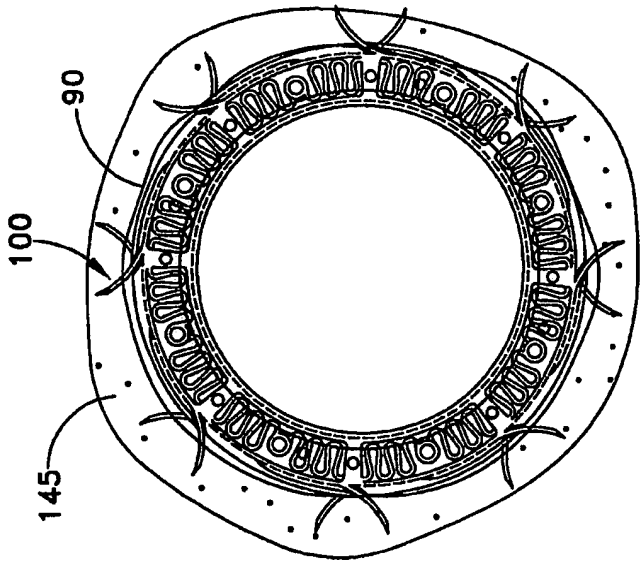

FIG. 13D

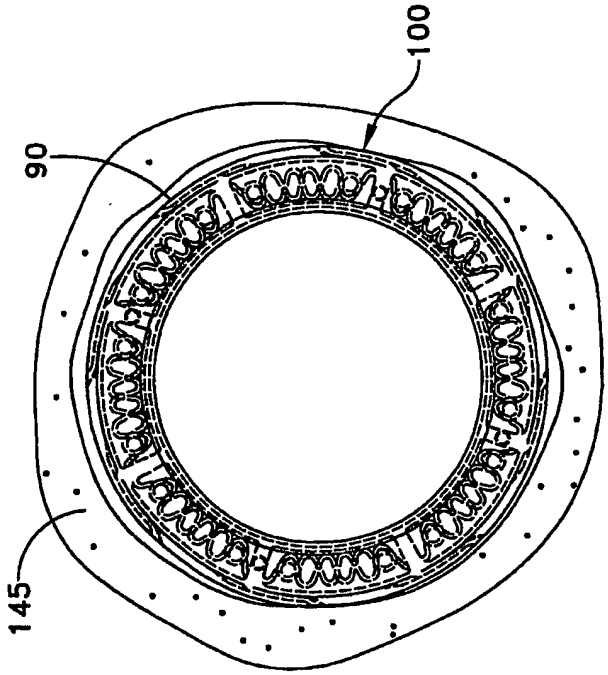

FIG. 13C

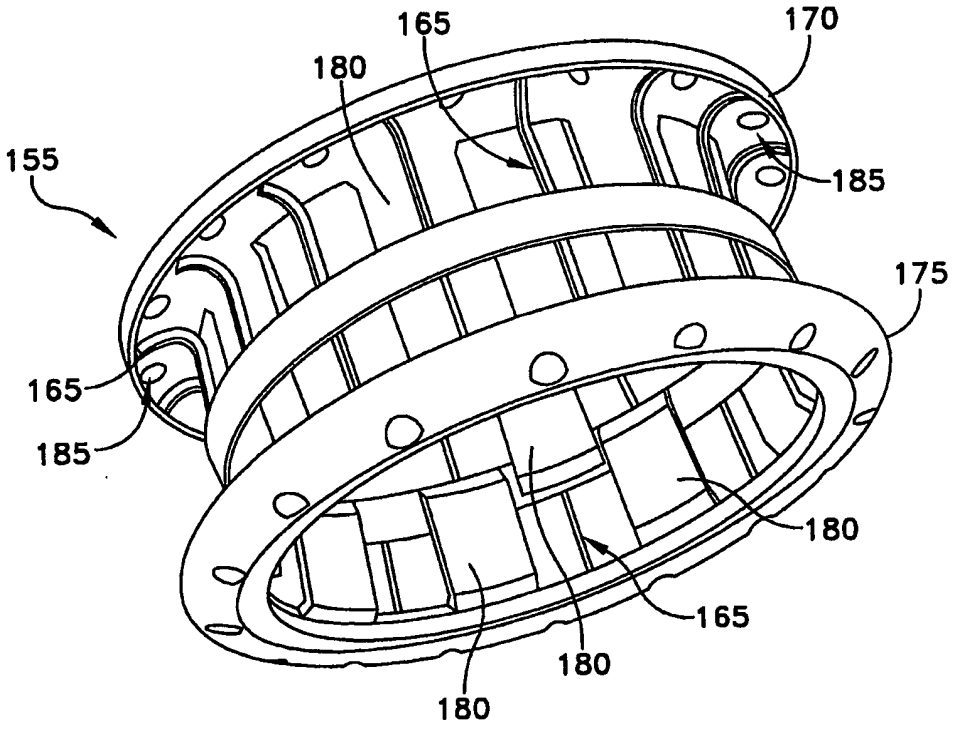

FIG. 14

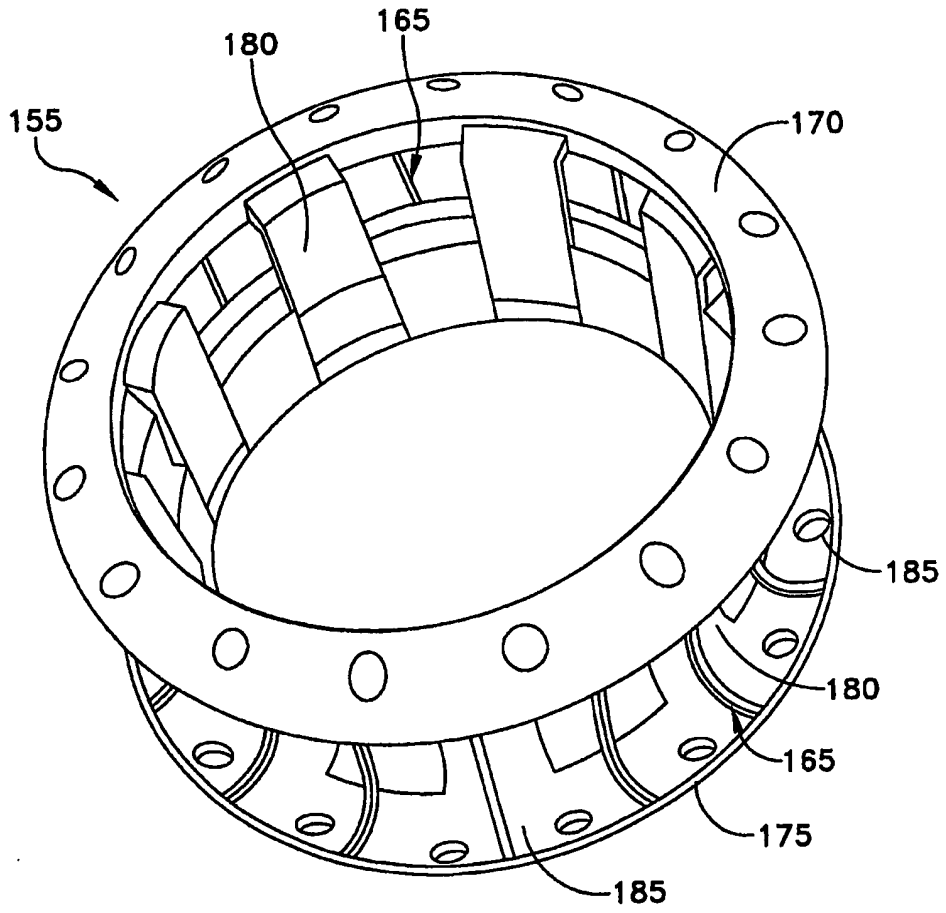

FIG. 15

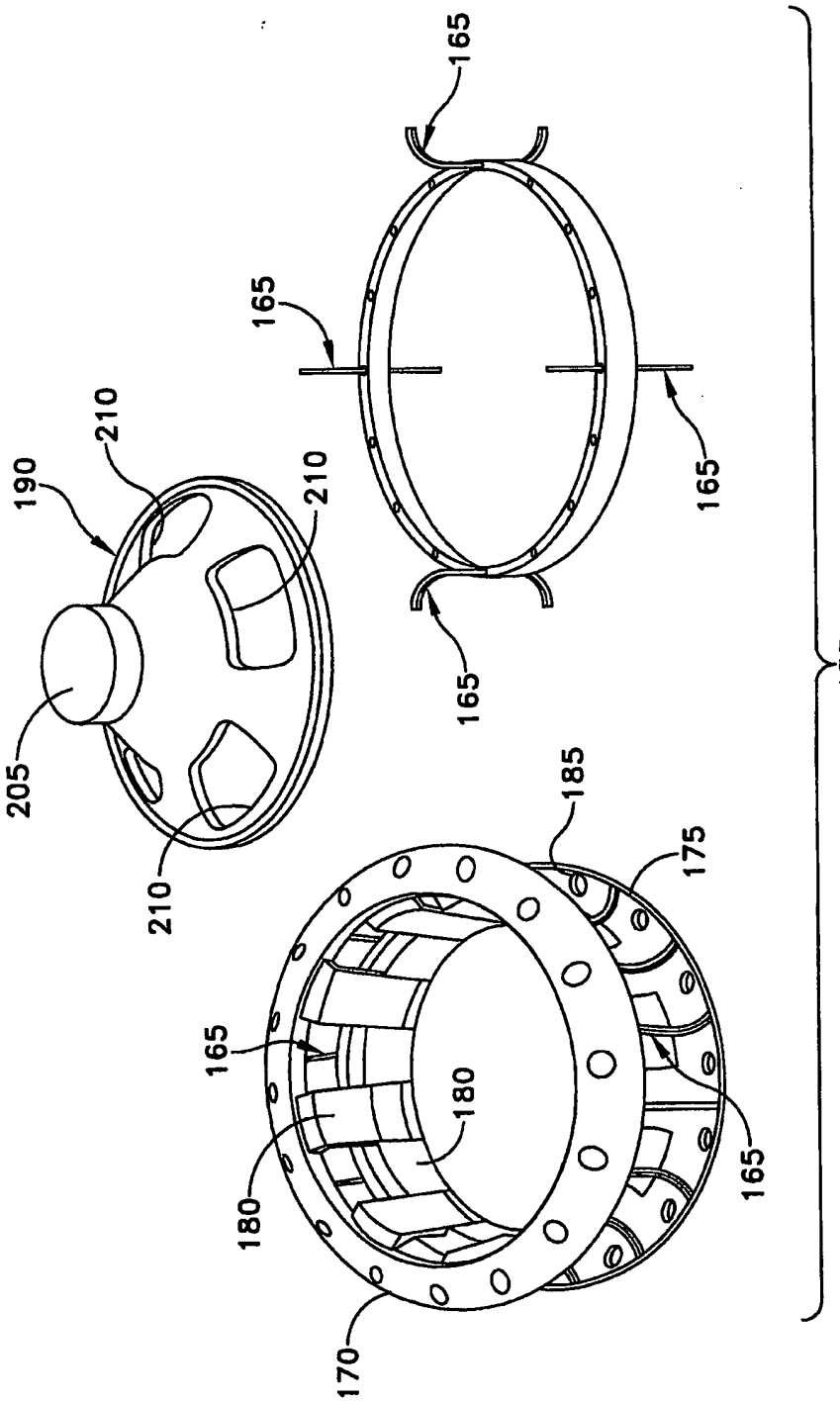
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FIG. 16

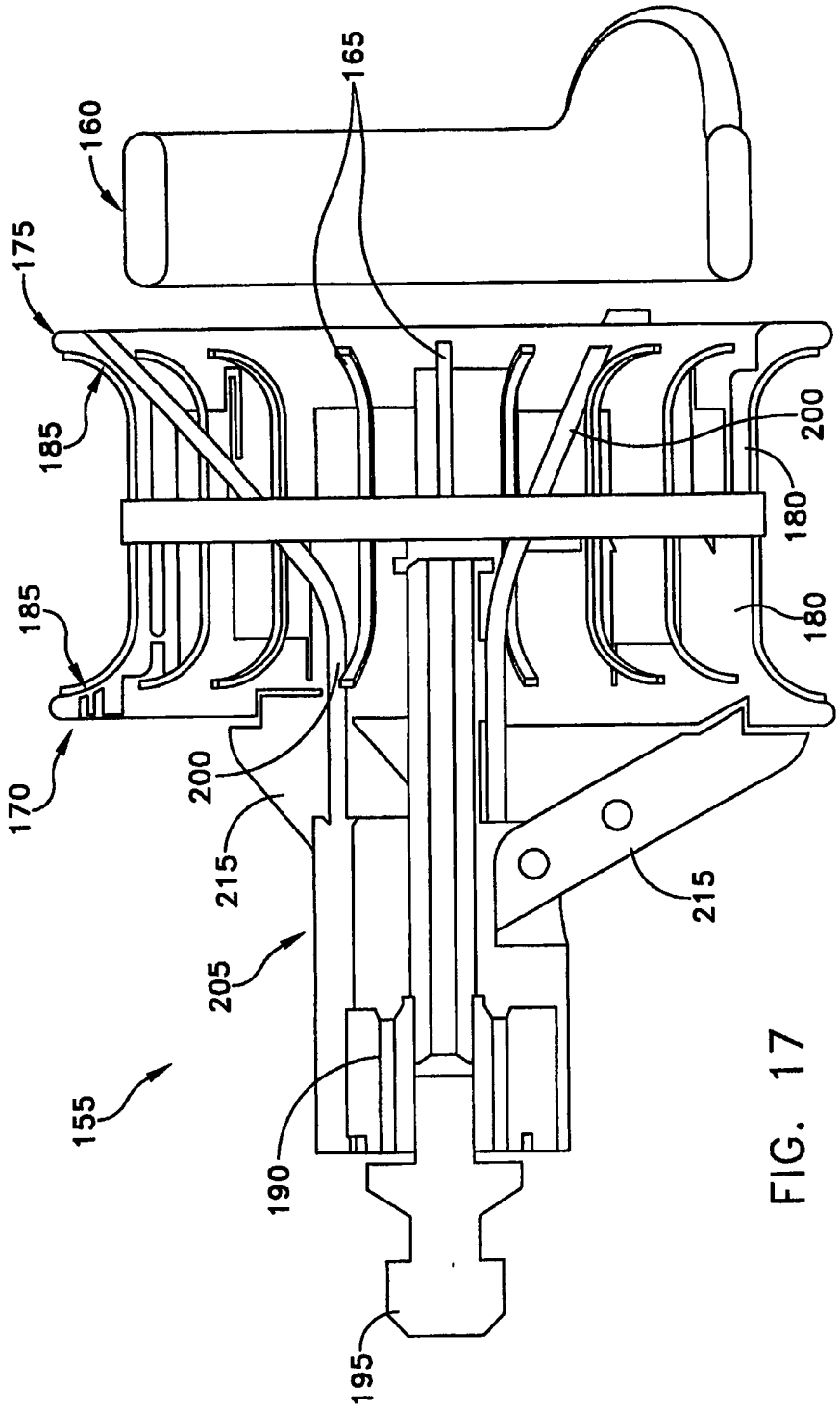

FIG. 17

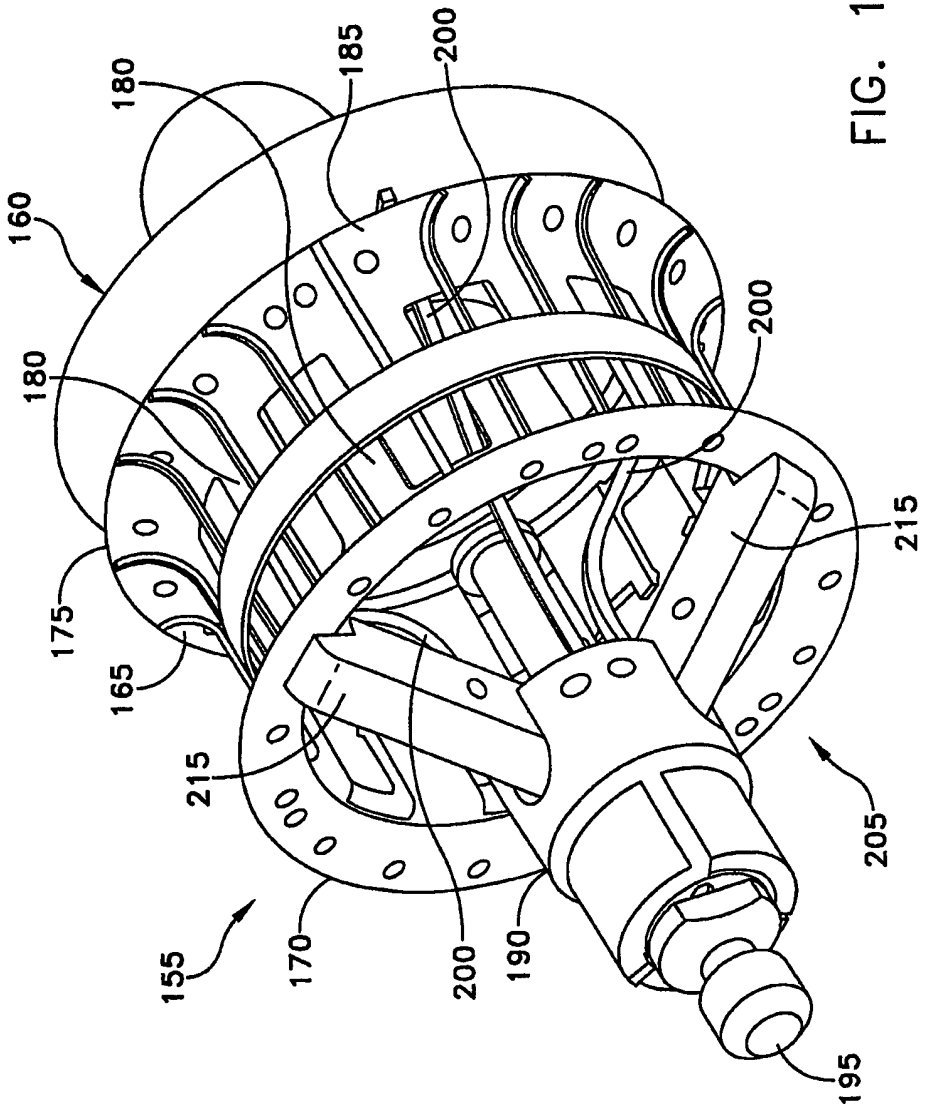

FIG. 18

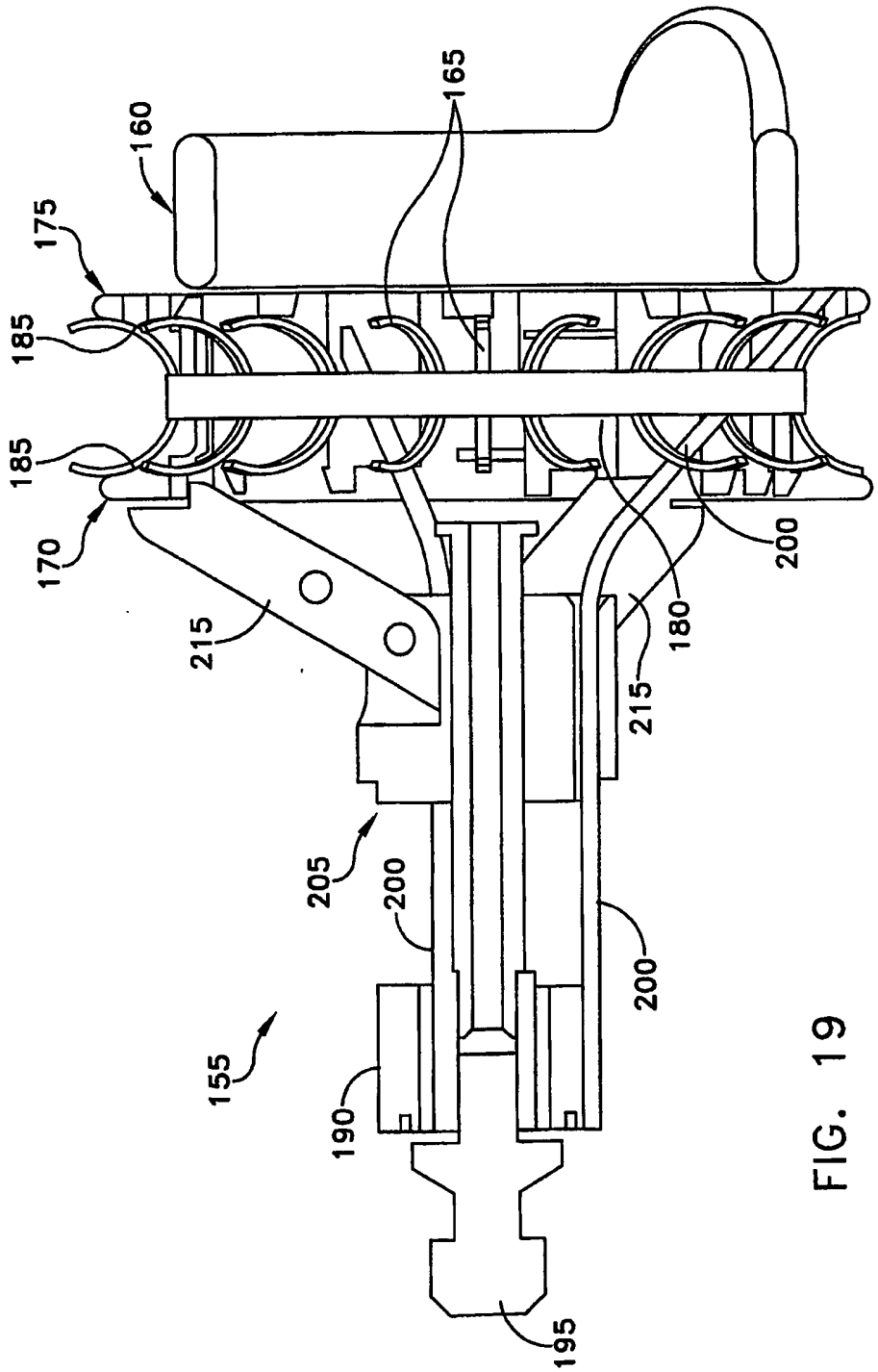

FIG. 19

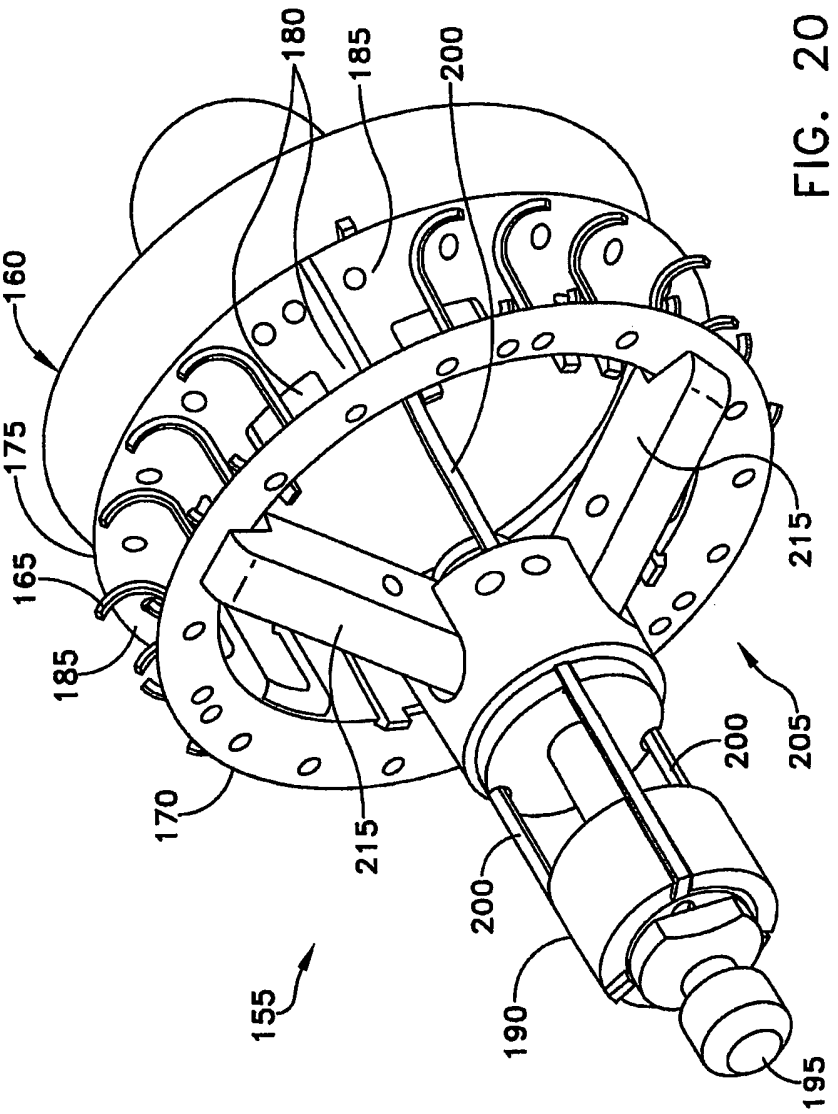

FIG. 20

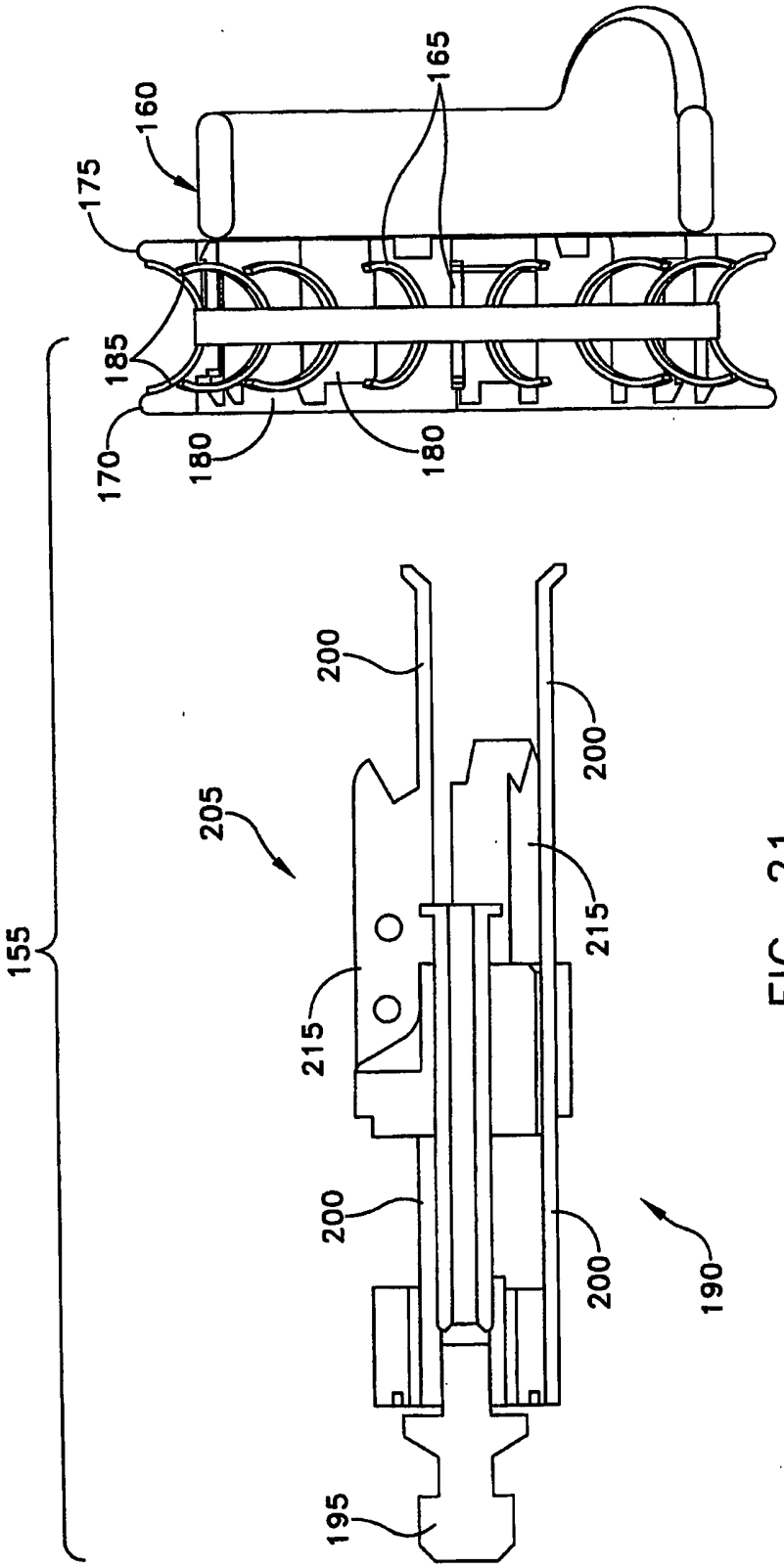
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FIG. 21

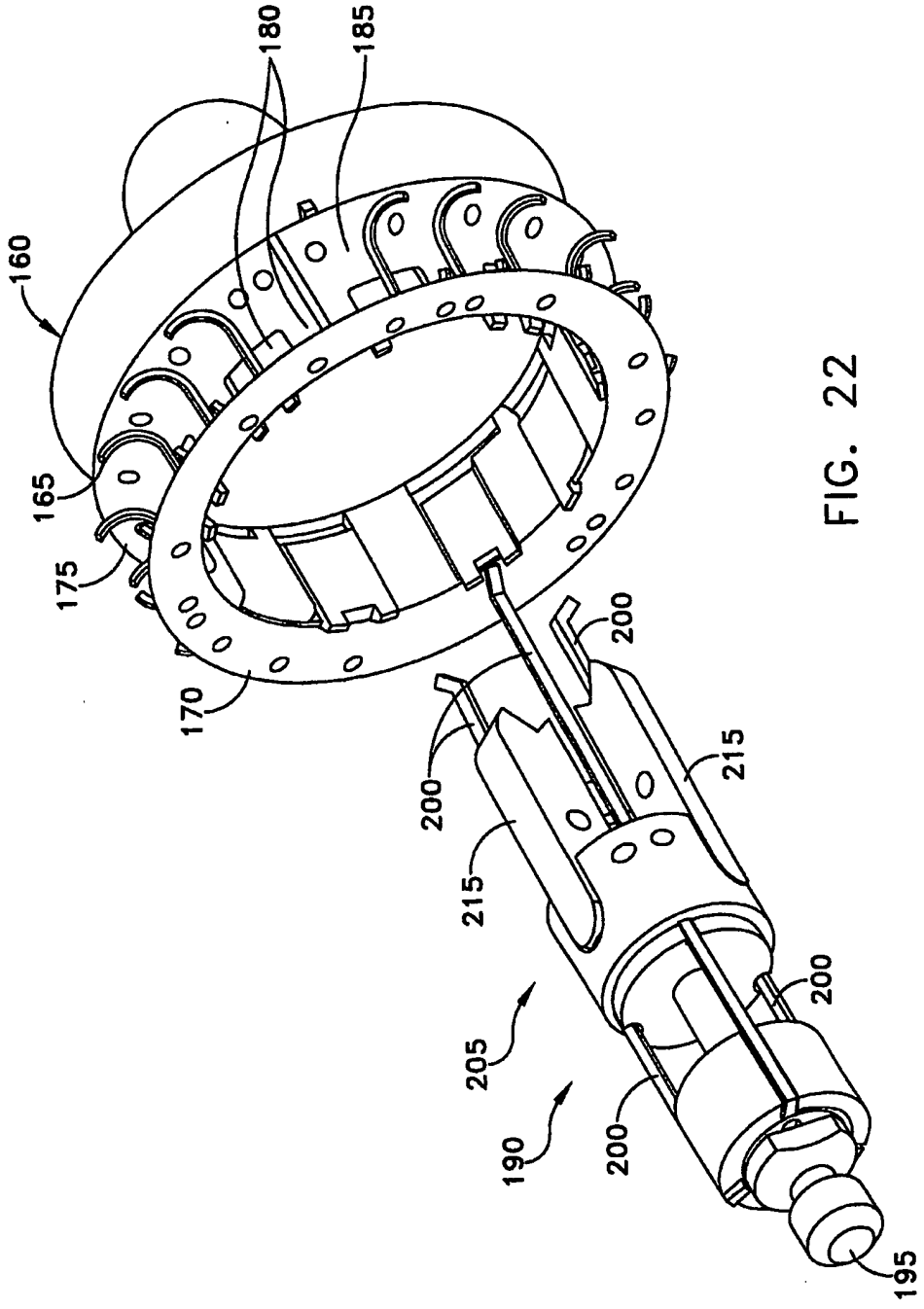

FIG. 22

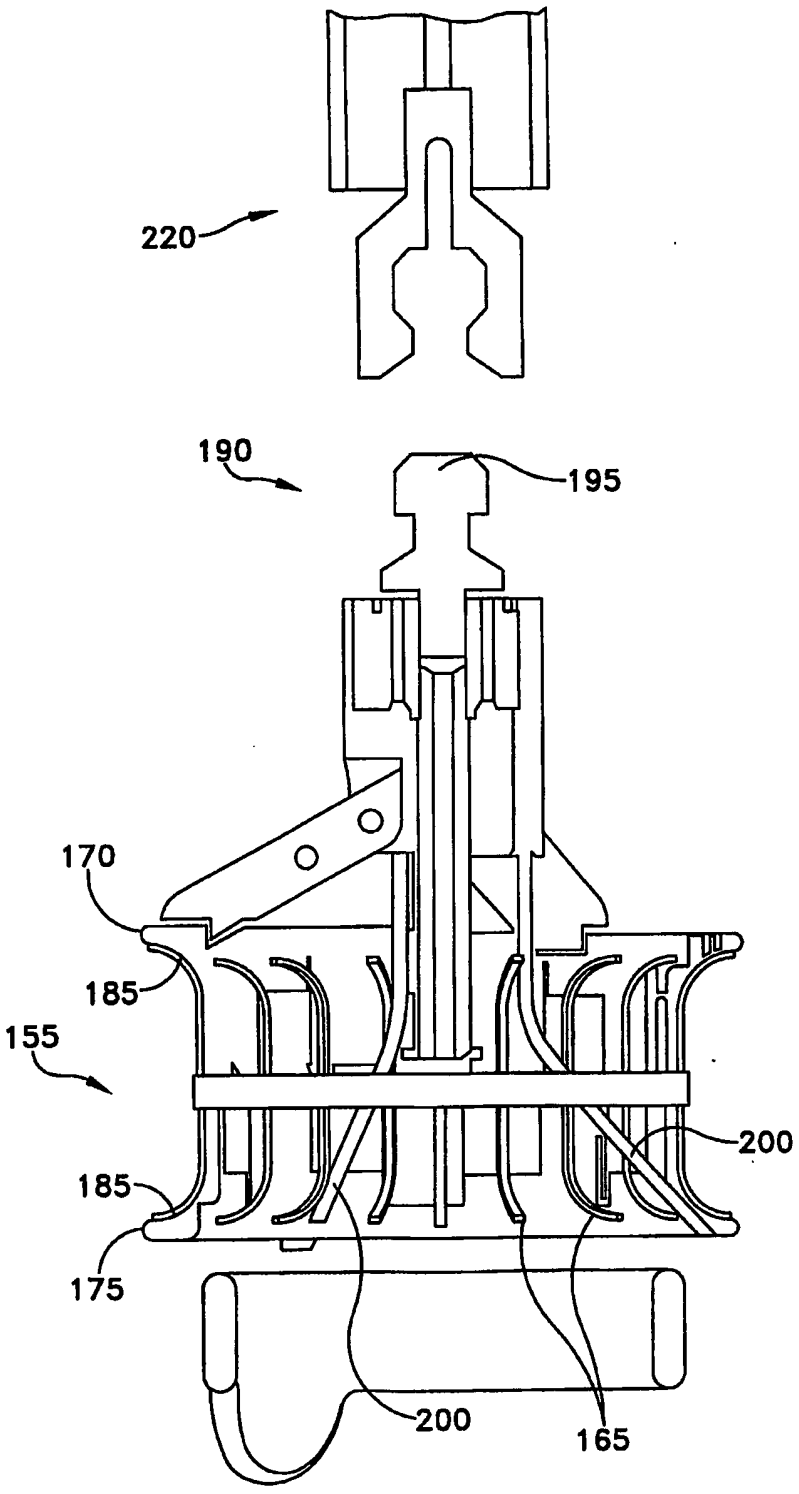

FIG. 23

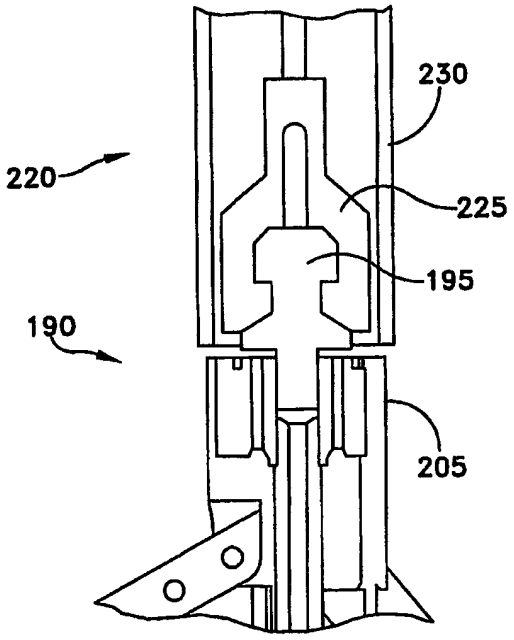

FIG. 24

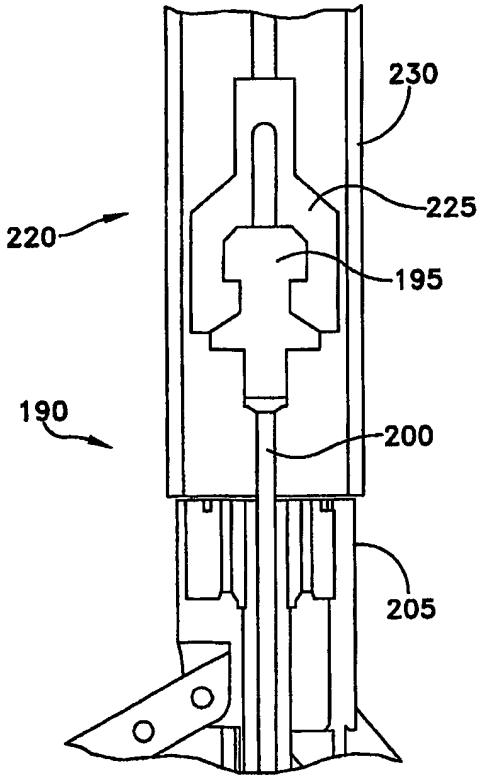

FIG. 25

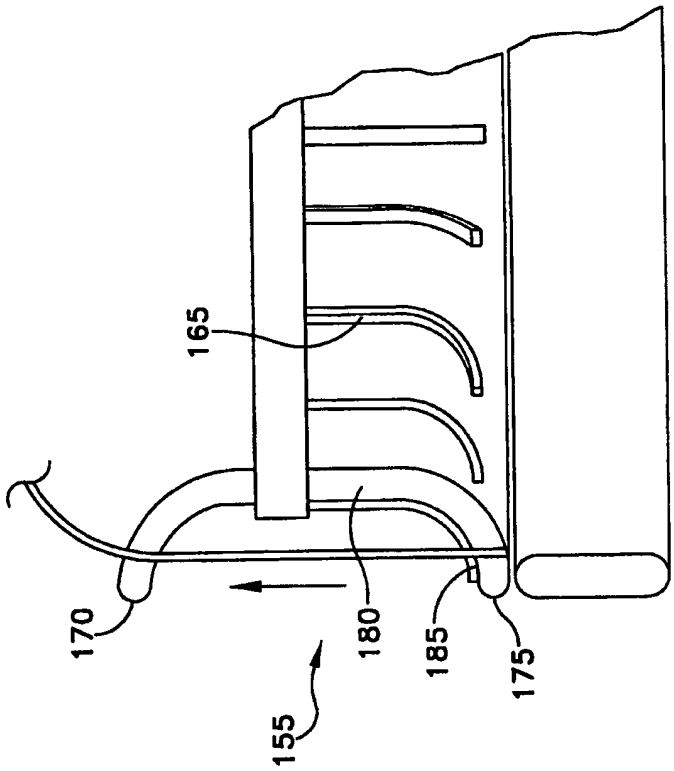

FIG. 26

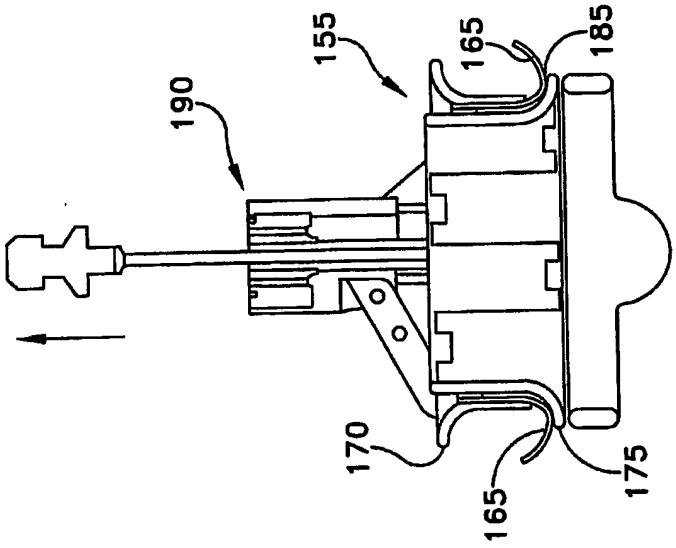

FIG. 29

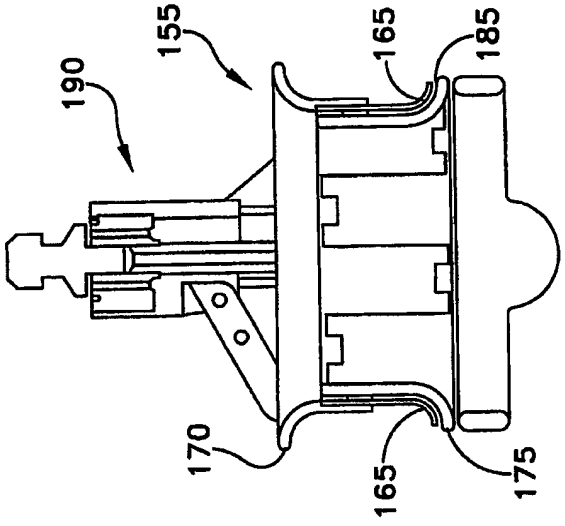

FIG. 28

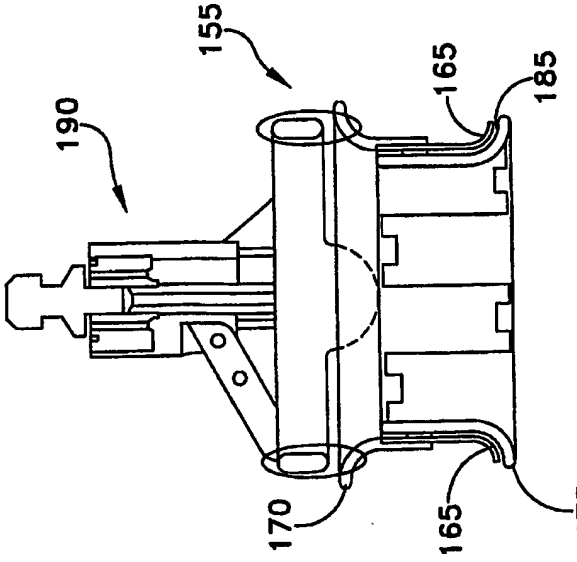

FIG. 27

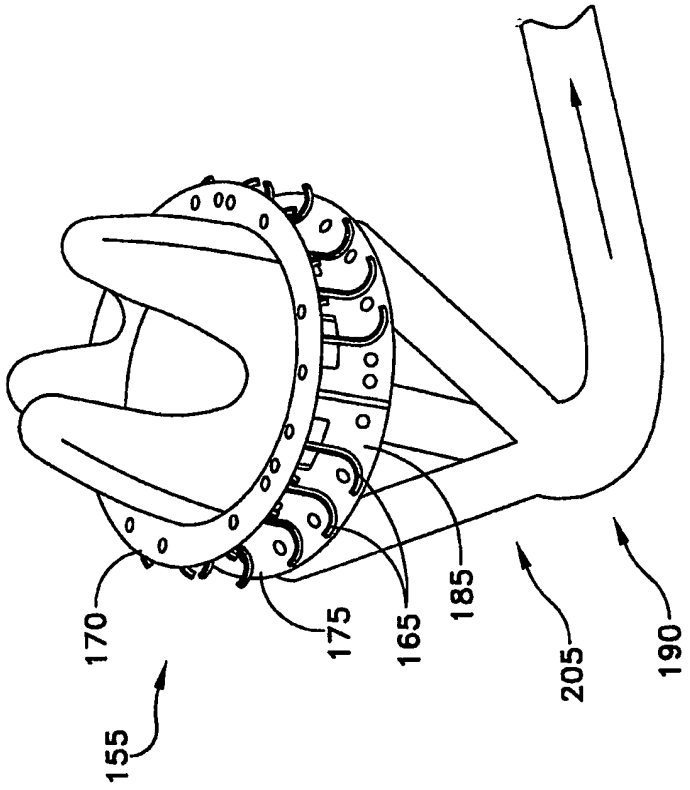

FIG. 30

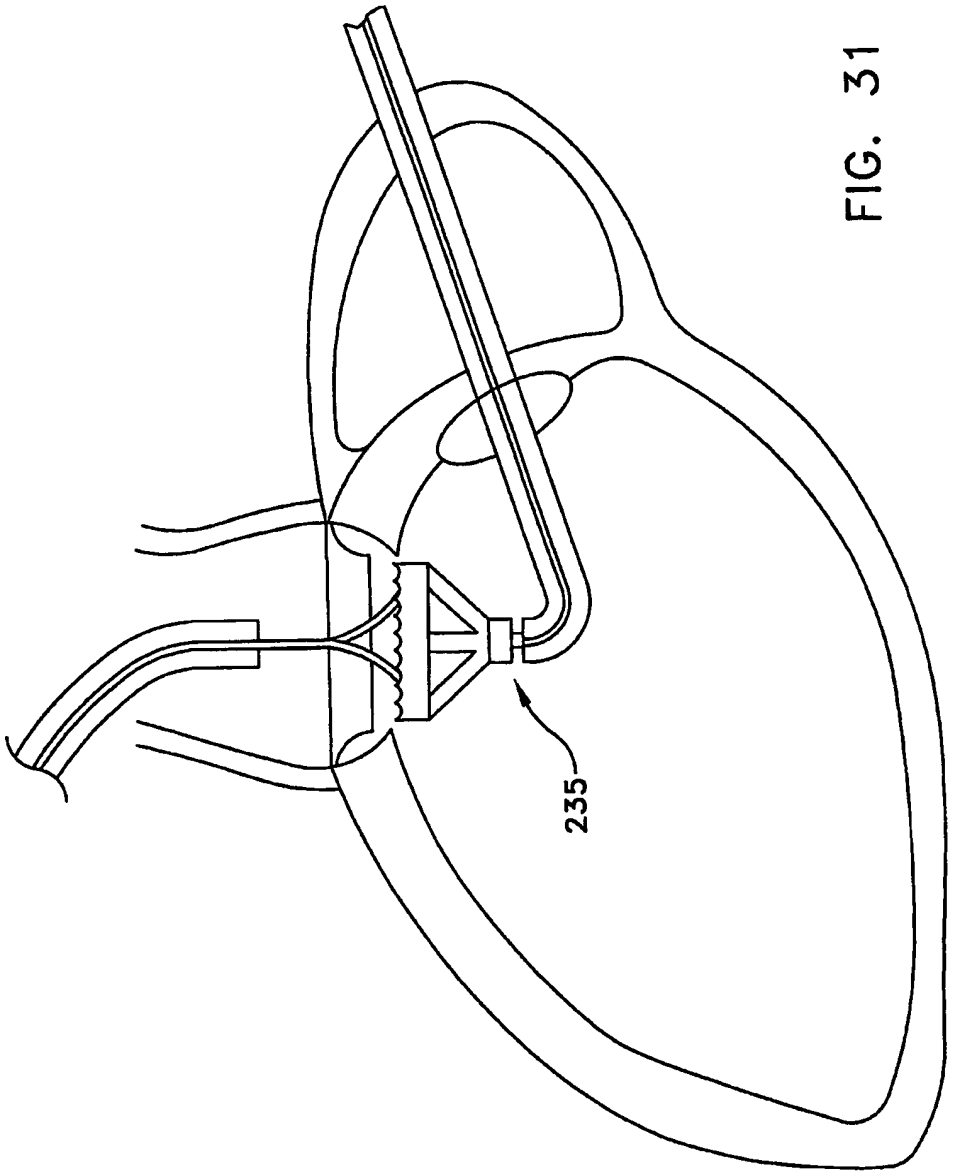

FIG. 31

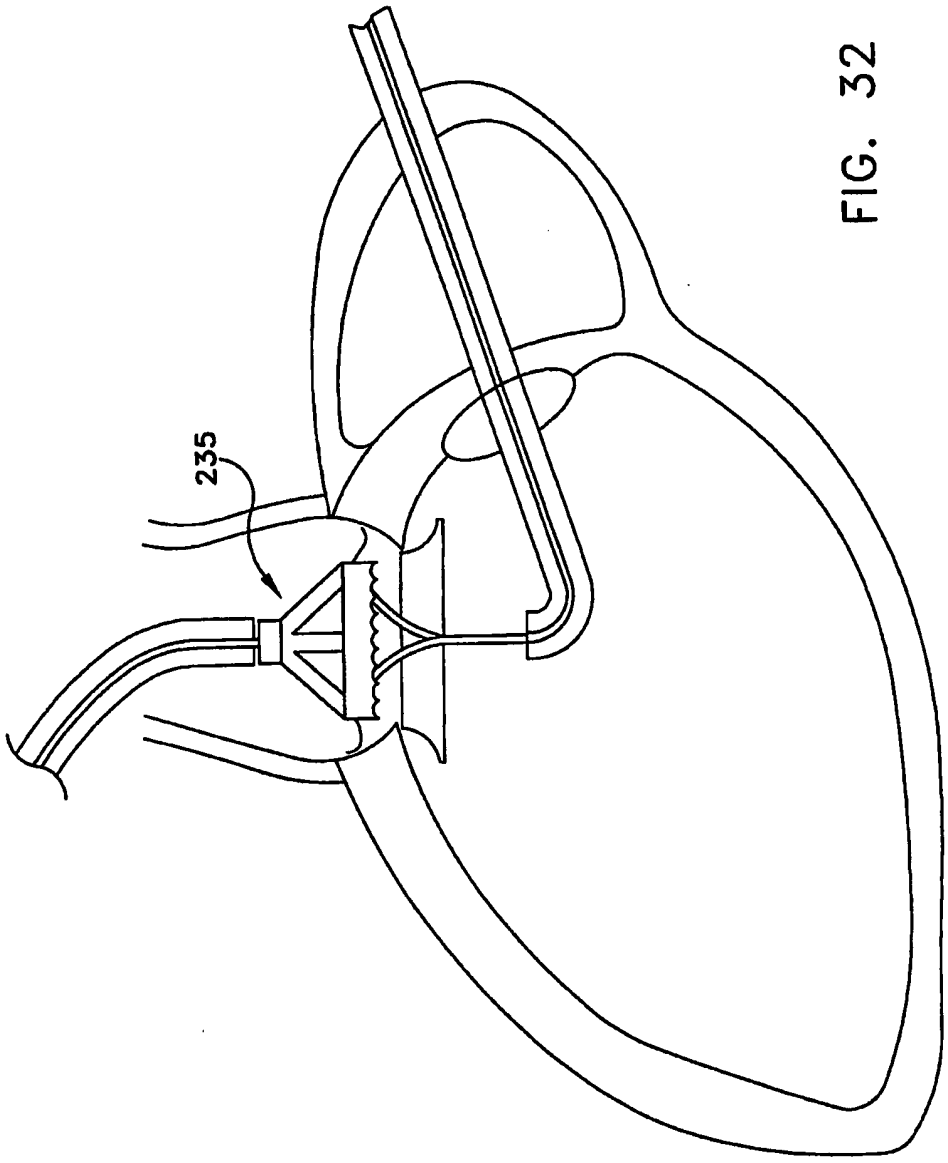

FIG. 32

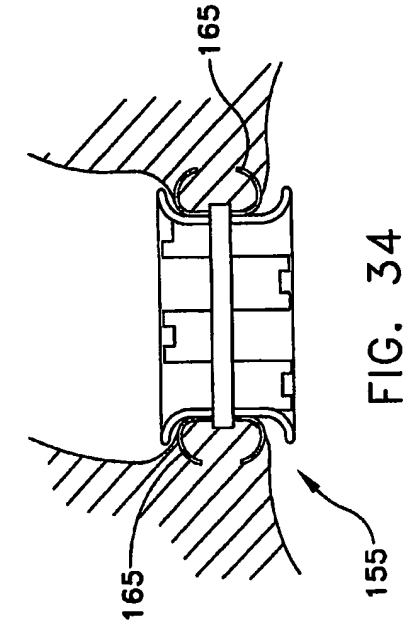

FIG. 34

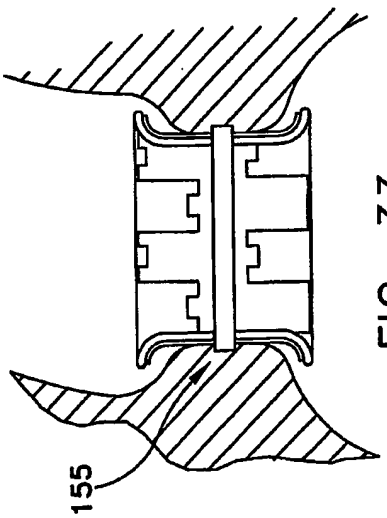

FIG. 33

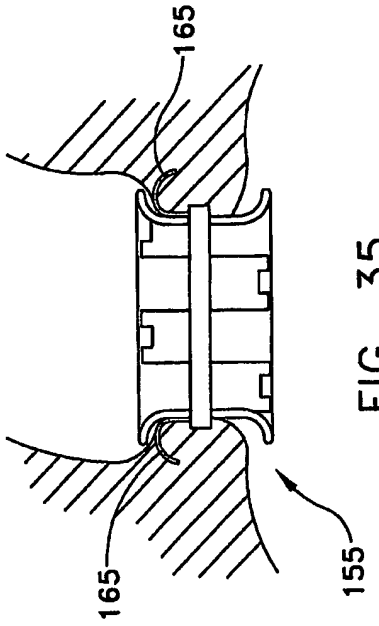

FIG. 35

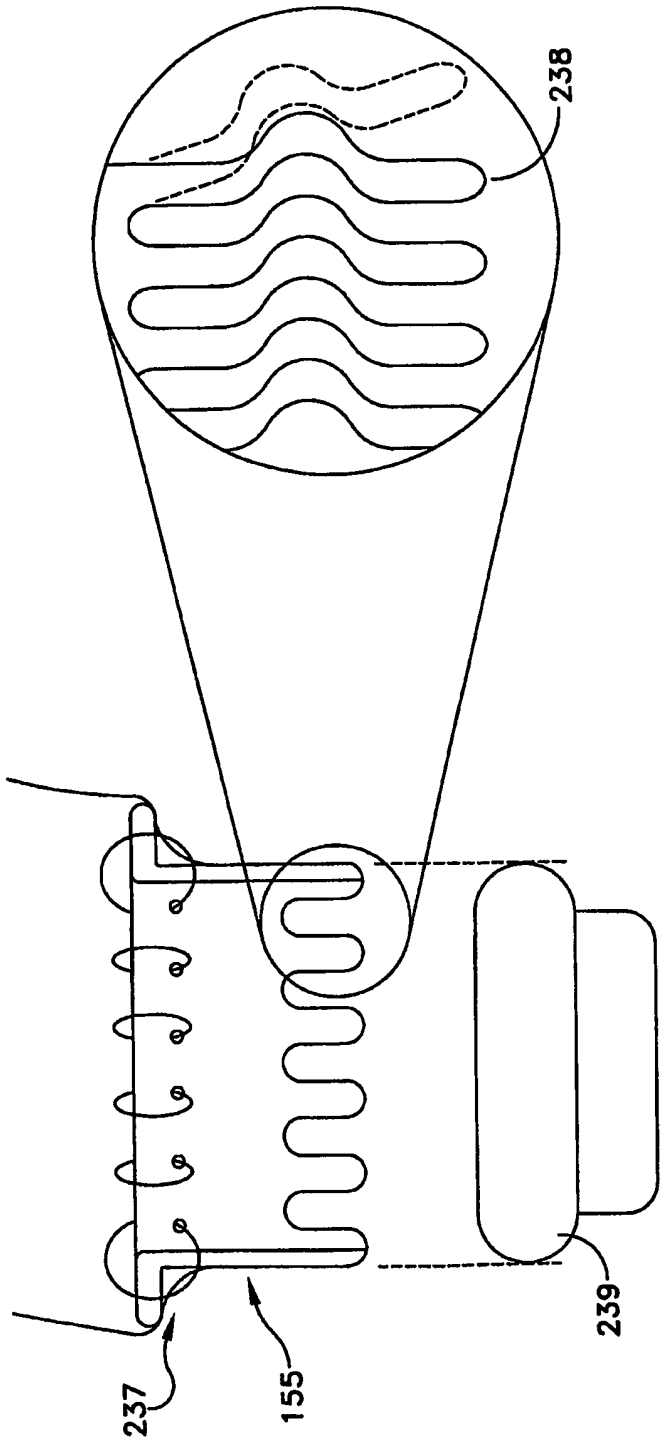

FIG. 36

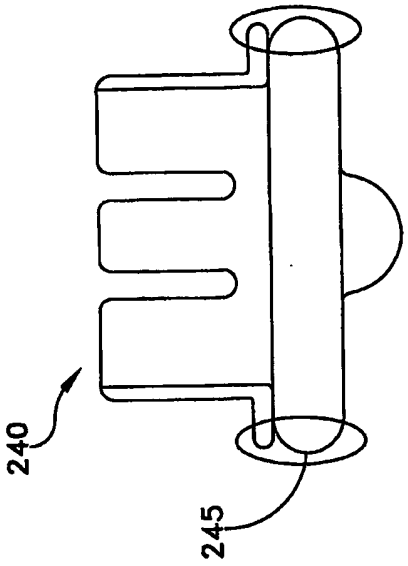

FIG. 38

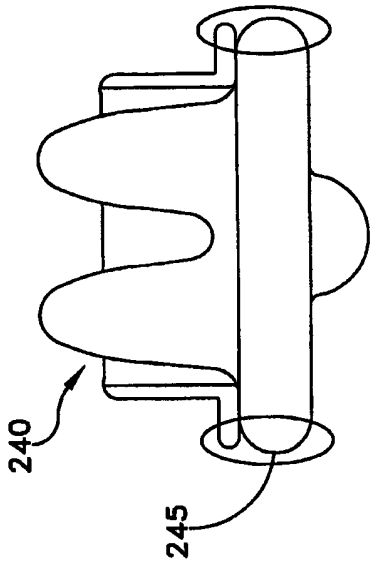

FIG. 39

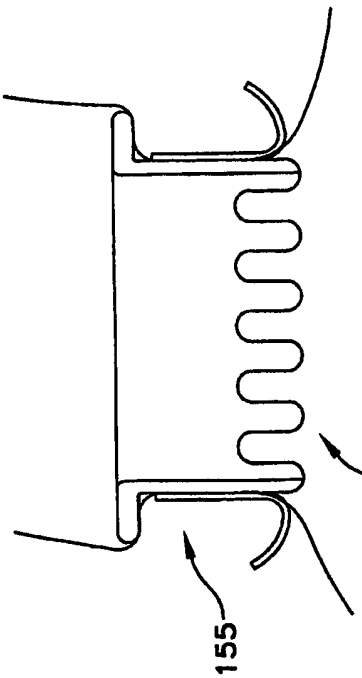

FIG. 37

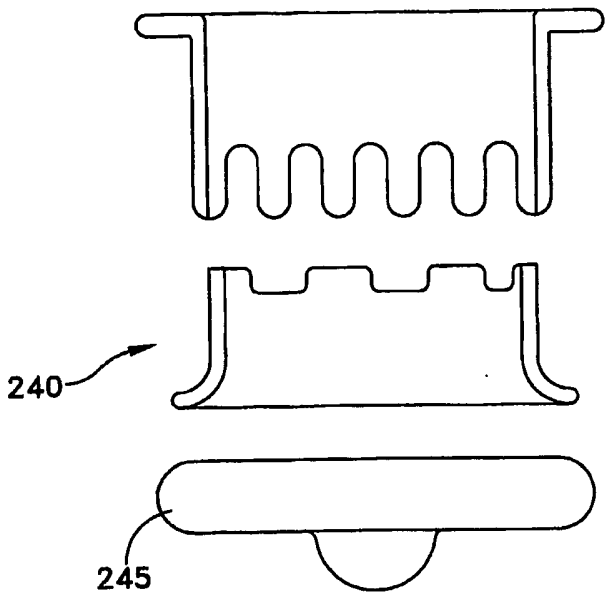

FIG. 40

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US03/11702

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61F 2/06
US CL : 623/2.38

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
U.S. : 623/2.38,2.39,2.4,2.1,2.11

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 3,143,742 A (CHROMIE) 11 August 1964 (11.08.1964), Figures 1,8-11 and column 2 line 5 - column 3 line 11.	1-3,9-11,13-16,18,19,22-27

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:

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"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search
27 June 2003 (27.06.2003)

Date of mailing of the international search report
11 AUG 2003

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